

SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED THIRTEENTH CONGRESS FIRST SESSION

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SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN

THURSDAY, APRIL 25, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:01 a.m., in room 2322 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Whitfield, Shimkus, Murphy, Blackburn, Gingrey, Lance, Cassidy, Guthrie, Griffith, Ellmers, Upton (ex officio), Pallone, Dingell, Capps, Schakowsky, Matheson, Green, Butterfield, Barrow, Christensen, Castor, Sarbanes and Waxman (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Paul Edattel, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Tom Wilbur, Digital Media Advisor; Jean Woodrow, Director, Information Technology; Alli Corr, Democratic Policy Analyst; Eric Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Nelson, Democratic Deputy Committee Staff Director for Health; and Rachel Sher, Democrat Senior Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Ten o'clock having arrived, the Subcommittee will come to order.

The Chair will recognize himself for an opening statement. There is an echo.

Members of this Subcommittee have been interested in securing our Nation's pharmaceutical supply chain for many years. While some supply chain provisions were included in Title VII of last year's FDA user fee bill, the Food and Drug Administration Safety and Innovation Act, FDASIA, a comprehensive track-and-trace package has yet to be finished.

Today's hearing will focus on the importance of securing the downstream pharmaceutical supply chain, which includes manufac-

turers, wholesale distributors, pharmacies, repackagers and third-party logistics providers.

In order to ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients, States have passed laws that require, or will require, those involved in the downstream supply chain to keep pedigrees or transaction histories of drugs.

Some believe that these differing State requirements should be replaced with a reasonable, practical and feasible federal policy.

On Monday, Representative Latta and Representative Matheson released a discussion draft to enhance the security of the pharmaceutical distribution supply chain and prevent duplicative or conflicting federal and State requirements.

I would like to thank all of our witnesses for being here today. I look forward to hearing their thoughts on the draft.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Members of this Subcommittee have been interested in securing our nation's pharmaceutical supply chain for many years.

While some supply chain provisions were included in Title VII of last year's FDA user fee bill, the Food and Drug Administration Safety and Innovation Act (FDASIA), a comprehensive "track and trace" package has yet to be finished.

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Some believe that these differing State requirements should be replaced with a reasonable, practical and feasible Federal policy.

On Monday, Rep. Latta and Rep. Matheson released a discussion draft to enhance the security of the pharmaceutical distribution supply chain and prevent duplicative or conflicting Federal and State requirements.

I would like to thank our witnesses for being here today. I look forward to hearing their thoughts on the draft. Thank you. At this time, I would like to request unanimous consent for Congressman Latta to participate in the subcommittee hearing. Without objection so ordered. I now yield the remainder of my time to Rep. Latta.

Mr. PITTS. At this time I would like to request unanimous consent for Congressman Latta to participate in this subcommittee hearing. Without objection, so ordered.

I now yield the remainder of my time to Representative Latta.

OPENING STATEMENT OF HON. ROBERT E. LATTA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. LATTA. Well, thank you very much, Mr. Chairman. I appreciate you having this legislative hearing today on this important issue of securing our Nation's pharmaceutical supply chain. I also appreciate the subcommittee for allowing me to participate in the hearing today.

This is an important issue that was brought to my attention when I was first elected to Congress over 5½ years ago by concerned stakeholders in Ohio, and I have been working on it ever since. I am pleased the subcommittee is holding a hearing on the

issue, and I am honored to be leading the effort in a bipartisan effort in this Congress.

The pharmaceutical supply chain touches every part of our health care system. It is imperative that we get the structure and the segments of it connected in a safe, secure and effective manner that provides the best protection for patients. This draft legislation Mr. Matheson and I have released on Monday is a commonsense, practical approach to making improvements to the current supply chain while facilitating continued collaboration among all parties before taking the next steps toward the additional requirements.

To protect patient safety, this bill would replace the patchwork of multiple State laws and create a uniform national standard for securing the pharmaceutical distribution supply chain, therefore, preventing duplicative State and federal requirements. It would increase security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies and repackagers based on—Mr. Chairman, should I just continue on without the mike?

Mr. PITTS. Go ahead.

Mr. LATTA. Thank you. It would increase security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies and repackagers based on changes in ownership. The bill also establishes a collaborative, transparent process between the Food and Drug Administration and stakeholders to study ways to further secure the pharmaceutical supply chain.

The timeline put forth in this bill is reasonable and would allow enough time for stakeholders to comply with these new national standards and ensure that through feedback from these stakeholders that the next phase of the process is done efficiently and effectively.

There has been significant work done on this issue over the years, and I appreciate all the feedback and suggestions I have received on this bill draft. While this bill is still in draft form, Mr. Matheson and I intend to introduce it in bill form in the coming weeks, and we fully understand that California law relating to implementation of an e-pedigree system is quickly approaching. It is imperative that we move this bill swiftly through the committee and then to the House Floor.

I look forward to working with our Senate colleagues on this legislation along with the FDA and all the other interested stakeholders, and I urge the support of this draft legislation soon to be in bill form.

Thank you, Mr. Chairman, and I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the ranking member, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE JR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts. I am pleased that we are having this hearing today because drug distribution security is critical to public health and safety. The public deserves the piece

of mind that the prescriptions they pick up contain quality ingredients and were handled throughout the supply chain by licensed companies adhering to strong safety standards so that the final products they receive are safe and effective drugs.

U.S. companies providing drugs to other international markets have already begun to serialize their products to comply with these countries' track-and-trace requirements, and the American people should be afforded the same protections.

Last summer, we had meaningful bipartisan bicameral conversations about this topic. While we were ultimately unable to reach an agreement, the discussions with our Senate counterparts and a number of stakeholders certainly demonstrated our commitment to the issue. As we revisit drug distribution security, there is a lot at stake, and that is why I am disappointed that we were not given the opportunity to work with our Republican colleagues on the draft bill that was released earlier this week. I am also concerned that this draft seems to me to not reflect where our discussions left off last year. Mr. Chairman, as we move forward, I urge the subcommittee to make sure we get this proposal right and that we work together to get there.

Now, some States such as California have already begun to address drug distribution security to ensure the safety of their patients. It is crucial that if we are going to preempt these State efforts, that we must have a strong federal standard. This standard should serve as a true building block to track drugs at the unit level so that each and every product is authenticated at the lowest unit of sale before they reach patients and counterfeit or contaminated products are eliminated. We cannot rely on Congress to revisit this issue in 10 years. The time to establish this path forward and set up phase-in requirements is now.

It is also important that everyone who is part of the system including the manufacturers, the repackers, the wholesale distributors, third-party logistics providers and dispensers play a role in tracing the safety of the Nation's drug supply.

In addition, I believe that in order to establish the most effective drug security system, it is critical that we include strong national license standards for distributors and third-party logistics providers so that only reliable companies are handling the Nation's drug supply, and FDA has immediate access to needed company information in the event of a drug recall or other public health threat.

I want to thank our witnesses here today including the FDA for all your hard work throughout this process. Many of you contributed to the discussions last year in a productive way to educate us on the supply chain process, and I look forward to better understanding what you believe is critically important to any bill that moves forward, and I want to extend a special welcome to Mr. Michael Rose, who is here testifying from Johnson and Johnson, which is headquartered in my district. I look forward to J&J and all the stakeholders as well as my committee colleagues to achieve a reasonable solution that will safeguard the public health.

I would like to yield the remaining 2 minutes of my time, Mr. Chairman, to our chairman emeritus, the gentleman from Michigan, Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank you for these hearings. I commend you and also my dear friend, Mr. Pallone. I want to commend Mr. Latta and Mr. Matheson for their leadership on this, which has been a long thorn in the side of this committee, being very, very difficult to achieve our purposes.

I would observe that we have before us an opportunity where the two parties are working together, where the House and Senate are working together, and I am delighted to see that that is happening because there is no real Democratic or Republican way of protecting the American public.

We have to work with all the stakeholders, and I have to observe that the pharmaceutical industry and the stakeholders have been most helpful in the matters as they have gone forward, and I want to thank again Mr. Latta and Mr. Matheson for their work on these matters. I am hopeful that we will be able to move forward toward legislation that will be accepted and acceptable to all parties, and I note that the industry has been working closely with us as has the Senate. It is my hope that we will understand that 10 years on some things within this matter might be a bit long, and I think that while we do need to see to it that Food and Drug has clear instructions from the Congress, we don't want to get to the point where we are micromanaging things and having meetings set up by Food and Drug which may or may not be of value to the country and to the industry and the consumers.

Having said those things, I would return 22 seconds to my dear friend from New Jersey, who has been so gracious as to yield to me.

Mr. PITTS. The Chair thanks the gentleman and now recognize the chairman of the full committee, Mr. Upton, for 5 minutes for opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman, and hopefully the mic will work long enough before our helium bill gets to the floor.

I appreciate today's hearing, and that is for sure, on securing the prescription drug supply chain. Keeping our prescription drugs safe is certainly a bipartisan issue, and we have the world's safest drug supply, but that doesn't mean we can't make it even better.

I would like to thank the discussion draft's authors for their bipartisan leadership on this very important issue. Earlier this week, as has been noted, a comprehensive discussion draft was released that would increase the security of the supply chain for America's patients while at the same time preventing duplicative Federal and State requirements. The draft also sets forth a collaborative process so the Food and Drug Administration and supply chain stakeholders could work together in an effort to better understand how and when to move to unit-level traceability.

We spent a significant amount of time working on this issue as we successfully moved the Food and Drug Administration Safety and Innovation Act through the legislative process in 2012 and our efforts continued beyond enactment. During that process, we also sought input from stakeholders like Pfizer and Perrigo, two important companies in my district in Michigan, as well as our small

pharmacies. This hard work allowed us to better understand the issue, and the bipartisan discussion draft reflects that understanding. Now it is time to move this legislation down the field and across the goal line. We have a lot of good friends in the Senate that agree with us on that sentiment, and it is certainly a priority for this committee to get this done, and I look forward to embarking on that, and I yield to Dr. Gingrey and then to Ed Whitfield.
[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Thank you for holding today's hearing on securing the prescription drug supply chain. Keeping our prescription drugs safe is a bipartisan issue. We have the world's safest drug supply, but that does not mean we cannot make it even safer.

I would like to thank the discussion draft's authors for their bipartisan leadership on this very important issue. Earlier this week, a comprehensive discussion draft was released that would increase the security of the supply chain for America's patients while at the same time preventing duplicative federal and state requirements. Their draft also would set forth a collaborative process so the Food and Drug Administration and supply chain stakeholders could work together in an effort to better understand how and when to move to unit-level traceability.

We spent a significant amount of time working on this issue as we successfully moved the Food and Drug Administration Safety and Innovation Act through the legislative process in 2012 and our efforts continued beyond enactment. During the process, we also sought input from stakeholders like Pfizer and Perrigo in Michigan, as well as our small pharmacies. This hard work allowed us to better understand the issue, and the bipartisan discussion draft reflects that understanding. Now it is time to move this legislation down the field and across the goal line. I believe my good friends on the Senate side agree with that sentiment.

Because of the hard work that already has been put in on this issue, I am confident we can get a product to the president's desk by the August recess. I commit today that I will do all that I can to make it happen, including marking up the legislation in the Committee in May. Thank you. I yield to Mr. Latta.

Mr. GINGREY. I thank the gentleman for yielding.

Mr. Chairman, I am pleased that there has been generally bipartisan acknowledgement that a secure pharmaceutical supply chain is not only necessary for patient safety but becoming obtainable and tracking technology continues to improve, and I would hope that the legislation that is ultimately the result of this hearing today will balance both the reality of today's emerging technologies with the flexibility to change as the result of innovation. It is also necessary that we provide a clear and a concise list of expectations and directives to all companies up and down the supply chain. Steady industry progress toward increased drug security should not be impeded by a lack of clarity from Congress as to the ultimate goal of this legislation for both the sake of innovation and security and for the patients who may be adversely impacted from counterfeit or stolen drugs.

Thank you, and I yield the balance of my time to the gentleman from Kentucky, Mr. Whitfield.

Mr. WHITFIELD. Well, Dr. Gingrey, thanks so much, and thank you all for having this hearing today, and we certainly appreciate the witnesses being here.

Last week, I attended a forum over at Georgetown University with the title of "Combating the Threat of Counterfeit Pharmaceuticals", and I really was taken aback by the amount of money being made by organized crime and other groups and entering into the supply chain counterfeit prescription drugs.

Another point that came out, and I am delighted that Mr. Latta and Mr. Matheson have introduced legislation at the federal level because we know individual States are moving forth, California, I guess out in the front right now, and I think we need to set a federal standard in this issue because I heard a lot of concerns about individual States moving in this area, which can create real problems for the manufacturers, but we want to do it safely, and I really look forward to the testimony of the witnesses today.

I would also ask unanimous consent to simply submit into the record a statement from a company called Laser Lock Technologies, if that is acceptable. They are an anti-counterfeiting company.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. WHITFIELD. And with that, I would yield back.

Mr. UPTON. I just want to end by saying that this is a priority. We intend to start the markup process next month, May, and our goal will be to try and get a bipartisan bill to the President before the August recess. So we are going to work very hard and we appreciate all those that are here to help us achieve that goal.

Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the Ranking Member of the Full Committee, Mr. Waxman, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

Today's hearing will examine ways to improve the integrity of our drug supply chain. The entry of falsified and substandard drugs into our drug supply chain poses a grave public health threat. Time and again, we have read stories about patients getting drugs that were unsafe or ineffective counterfeits or that were stolen and not stored properly, so no longer worked. Without action, this is a problem that is likely to grow.

Today, there is a regulatory void at the federal level because the United States does not have laws requiring the tracking and tracing of pharmaceuticals. So some States have stepped in and enacted their own laws. My State, California, has a law that would mandate one of the most robust pedigree systems in the country. Many have suggested there is a need for a single federal system that would preempt these State laws. I believe having a system at the federal level makes sense, if done correctly. But I have grave concerns about preempting a strong State law like California's and replacing it with one that is not as effective at the federal level.

Our fundamental goal in establishing a federal system should be to prevent Americans from being harmed by counterfeit and substandard medicines. If we cannot assure the public that legislation would accomplish that goal, then it is not worth doing.

Throughout last year, members on a bipartisan, bicameral basis engaged in extensive discussions about how best to protect our supply chain. I was part of this group, as was Chairman Upton and Representatives Pallone, Dingell, Matheson and Bilbray. We heard loud and clear from FDA, Pew and others that if we want a secure

drug supply chain, we need an electronic, interoperable unit-level tracking system that can identify illegitimate product in real time so that it does not end up in the patients' hands. We also heard that creating this kind of system is doable. In fact, it is already being done in China, as we will hear today from one of our witnesses.

Last fall, the bipartisan, bicameral group issued a proposal that although far from being complete, reflected agreement about the need for assuring that we ultimately get to a unit-level electronic system. And just last week, the Senate distributed a draft bill built upon that proposal and made a concerted effort to address issues that were raised on both sides of the aisle throughout last year's discussions.

Unfortunately, the House discussion draft under consideration here today doesn't take that approach. The bill does not require an electronic, interoperable unit-level system. Instead, it provides that in ten years, FDA and GAO would make recommendations to Congress about what legislation should be enacted to better secure the supply chain. And even though we never get to a unit-level electronic system, the House bill would preempt State law on day one. That is unacceptable to me as a California member, but it should be unacceptable to all members. We know how long it has taken Congress to act thus far. The discussion draft preempts strong State laws and puts a weak federal program in its place. That is a step backwards for public health. There simply is no reason to wait to put enforceable standards in place. We have been told repeatedly, and I am confident we will hear today, that in order to secure our drug supply chain, we need to track products at the unit level using an interoperable, electronic system. We fail to protect the Nation's public health if we do not take this step. I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman. That concludes the opening statements of the members.

We have two panels before us today. On our first panel, we have Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Welcome. Thank you for coming today. You will have 5 minutes to summarize your testimony. Your written testimony will be placed in the record. You are recognized now for 5 minutes.

STATEMENT OF DR. JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

Dr. WOODCOCK. Thank you, and good morning Mr. Chairman, Ranking Member, members of the subcommittee and authors of the discussion draft.

We are all seeking the best way to protect patients from medicines that aren't what they pretend to be. That is why we are here. Or that may cause harm to them without providing the help that they expect from their medicine, and that is the goal we want to achieve mutually. So I thank you for continuing to work on this program. We hope to do this by strengthening the safety net that we currently have in place for medicines so that counterfeit drugs can't get in the drug supply because right now there are some loop-

holes where they can enter the drug supply, and they are. Diverted or stolen drugs can't reenter the drug supply after being perhaps taken by criminals and stored in unsafe conditions, and suspect products that happen to get in can be rapidly identified and removed from the drug supply before they get to patients. And additionally, we need to be able to find drugs wherever they are in the supply chain. If dangerous products have been dispensed to patients, we want to be able to find them and get them out of the hands before the patients are harmed.

And why do we need this? Well, as people have already said, the problems with counterfeits are well documented and actually growing. Around the world, criminal networks are counterfeiting drugs at a growing rate and many countries, their patients in their countries are exposed to very dangerous drugs and even some of the organisms, the resistance problems that we are seeing with drug resistance, are partly driven by these counterfeits because people are taking drugs that actually are subpotent that are counterfeit drugs. And we are seeing this in the United States where often expensive, lifesaving medicines are targeted. I can't imagine what it is like for a person battling cancer to hear that they have been receiving a fake therapy or their cancer or for a diabetic to lose blood sugar control because their insulin came from a stolen batch that was improperly stored, and these things actually have happened in our country.

And there are other equally compelling reasons to strengthen drug track and trace that we haven't really discussed as much, and that is to enable recalls of FDA-approved drugs. This is really a non-trivial problem. Over the last 5 years, there have been over 6,500 drug recalls in this country. Over 400 of these have been class I recalls, and a class I recall is where our doctors at FDA have determined that there is an immediate risk to health if people would take these drugs, serious risk. And we need to be able to find these recall drugs, as I said, and get them out of the hands of patients rapidly. For example, this has happened, there could be a label mix-up and what is labeled as an innocuous drug, perhaps a pain reliever or something, could actually have a dangerous drug such as a blood thinner or cancer chemotherapy drug in that vial, and so if that type of thing happens, we need to be able to rapidly identify the patient who may have these drugs and get them right down to the patient level.

So right now, we have a great deal of difficulty finding which patients got these drugs, particularly at the lot level. What we may end up doing is recalling the entire drug, and sometimes these drugs are lifesaving drugs that we don't want to remove completely from the patients; we only want to get the tainted lots. So this is a large and growing problem, and good track and trace would help the entire health care system, people taking care of these patients to secure these products as soon as possible and avoid further harm.

And finally, I think and most importantly, I want to say, whatever is put in place by Congress should not fray or weaken the existing safety net. A recent investigation conducted by your colleagues' Ranking Member Cummings of the House Oversight and Government Reform Committee and Chairman Rockefeller and

Chairman Harkin in the Senate identified a gray market of business that was capitalizing on the way drugs can move through the system to buy up drugs and resell them, perhaps at 1,000 times markup that were in shortage, and desperate hospitals, saying caring for children with cancer had no choice to buy these drugs at this markup because they had to treat their patients. So the existence of that paper pedigree, as noted in the report, enabled them to track back each transaction and figure out the markup and document what actually happened with these shortage drugs. So this paper pedigree right now is a mainstay of us figuring out where those drugs have been, not always followed but that is the law that they should have that pedigree and we mustn't weaken that, so I really ask you that any system that you put in place not diminish our ability to figure out where these drugs have been. It was astonishing if you read the Cummings report the Murphy trail these drugs followed and their successive markup as they went through multiple hands, none of whom, arguably, had a real interest in getting these drugs to patients. They were simply marked up at each step.

So we really ask that we not lose the ability to figure out where drugs have been. That is critical, and we recognized that changes will not happen overnight and a stepwise process is needed, but it should be expeditious. There are technologies available in various industries that can track things. I order a lot of things online so many of you do too and they are tracked throughout the system.

So we have to make sure we strike the appropriate balance between the need to establish a secure system that protects the public health and the costs and feasibility of such a system and we need to make sure we put something in place, I think, that evolves over time to a common goal that we all have is a system that prevents criminals from taking advantage of our patients, prevents people from diverting drugs and marking them up, prevents us not being able to identify recall drugs and actually people being harmed while we are doing investigations and trying to figure out where these drugs ended up.

Mr. PITTS. Could you please conclude?

Dr. WOODCOCK. I am sorry. So our ultimate goal, as yours, is to protect the public from counterfeit, stolen, diverted or unfit medications and make sure that we establish a meaningful and enforceable track-and-trace system. Thank you.

[The prepared statement of Dr. Woodcock follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

**STATEMENT
OF
JANET WOODCOCK, M.D.
DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH**

**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES**

"SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN"

APRIL 25, 2013

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member Pallone and Members of the Subcommittee, I am Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important issue of securing the supply chain for prescription drug products.

Securing the Supply Chain for Prescription Drugs

As FDA has previously testified before this Committee, the increasingly complex drug supply chain, from raw source materials to finished products for consumers, presents multiple opportunities for the product to be contaminated, diverted, or otherwise adulterated. Our efforts to secure the supply chain include minimizing risks that arise anywhere along the supply chain continuum, from sourcing a product's ingredients through the overseeing of a product's manufacture, storage, transit, sale, and distribution. A breach at any point in this continuum could lead to dangerous and even deadly outcomes for patients.

In addition, we continue to see counterfeit drugs threaten American consumers' health.

Counterfeit drugs raise significant public health concerns, because their safety and effectiveness are unknown. A counterfeit drug could contain a substance that is toxic to patients. But even a counterfeit drug with no active ingredient could prove harmful to patients who take it, thinking that they are taking a lifesaving or life-sustaining medication, when they are not. For example, in 2003, over \$20 million in illegally imported and counterfeit Lipitor (atorvastatin calcium), a popular cholesterol-lowering drug, was distributed throughout the United States. The source and

manufacturing methods of these drugs were unknown and therefore had the potential to endanger patients. As another example, in 2012, FDA learned of counterfeit versions of two controlled substances that were being sold on the Internet: Adderall (amphetamine aspartate), a drug used to treat attention deficit disorder, and Vicodin ES (acetaminophen; hydrocodone bitartrate), a drug used to treat pain. In both of these incidents, the counterfeits contained different active ingredients than the products they purported to be. Also in 2012, FDA alerted over 500 U.S. medical practices that they had purchased unapproved drugs, some of which may have included a counterfeit version of a cancer medicine. At least some of the counterfeit drugs contained no active ingredients. These examples are troubling because patients may not have received needed therapy or may have experienced harmful side effects.

Counterfeit drugs are not the only problem; stolen or diverted products also pose a threat to patients. Once products leave the legitimate supply chain, we have no idea how they are being stored or handled—or even if they have expired. When those drugs make their way back into the supply chain, they can pose a danger to patients. For example, in one case in 2009, approximately 129,000 vials of Levemir (insulin detemir) were stolen. Insulin is used to control blood sugar levels in patients with diabetes and should be stored in a refrigerator before use. A patient who received the stolen insulin had poor blood glucose control, likely as a result of it not being stored properly. In 2008, a shipment of Carbatrol (carbamazepine), a drug to treat seizures, was stolen while traveling from a company's manufacturing facility to its distribution center. The manufacturer reported that expired Carbatrol from the stolen lots made it back into the legitimate supply chain and was being returned for credit. In a case from 2011, a criminal diverted \$2.7 million in prescription drugs by purchasing them from physicians who get

discounted rates, and then reselling them to wholesalers at a profit. These diverted drugs included sterile injectable drugs, which usually require special storage and handling.

While we recognize that we may not be able to eliminate all problem products from the supply chain, we take every step we can to make the supply chain more secure to keep the illegitimate products out. Implementation of a system to fully track and trace prescription drugs throughout the supply chain would help in combating incidents like these counterfeit examples. In February 2013, the Institute of Medicine issued a report entitled “Countering the Problem of Falsified and Substandard Drugs,” identifying a combination of actions that could reduce counterfeit and substandard drugs domestically and globally. The report recommends implementing a mandatory drug tracking system in the United States and recognizes how knowledge of where a product is and where it has been can greatly reduce the risks introduced by product diversion and porous supply chains.

A robust track-and-trace system, in which each drug produced would be tracked as it passes through the distribution system and allows purchasers to verify its distribution history, would improve the ability to identify and detect potentially harmful products if they enter the supply chain. Another potential benefit would be to improve the efficiency of product recalls. Imagine a system that enables the distributor or pharmacist to readily determine if they have sold or now have in stock a drug that had been identified as a counterfeit or subject to a recall. They could quickly remove that product from the supply chain, keeping the patient out of harm’s way. The only way this can be done effectively is if all supply chain stakeholders participate in the system and if all legitimate products have a way to be identified and tracked as they are distributed from the point of manufacture.

FDA's Current Activities

The Food and Drug Administration Amendments Act of 2007 (FDAAA; Public Law 110-85) gave FDA authority to set standards for identification, validation, authentication, and tracking and tracing of prescription drugs; but, it did not provide the Agency with explicit authority to require an effective track-and-trace system for all drug products throughout the supply chain. In March 2010, FDA issued a final guidance for industry describing the Agency's current thinking for standardized numerical identification (also known as serialization) for prescription drug packages. This guidance was the first of several steps that FDA intends to take to implement these provisions of FDAAA. We held a Track-and-Trace Public Workshop in February 2011 to obtain public input on the necessary elements to achieve effective authentication and the desirable attributes of a track-and-trace system. FDA continues to work on developing these standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA; Public Law 112-144) provided the Agency with new authorities that will help to secure the safety and integrity of drugs imported into, and sold in, the United States. For example, the law includes provisions that allow FDA to refuse admission of a product to the United States if inspection of the manufacturing facility is delayed, limited, or denied; require foreign and domestic companies to provide complete information on threats to the security of the drug supply chain; and improve current registration and listing information, making sure FDA has accurate and up-to-date information about foreign and domestic manufacturers. A robust track-and-trace system would complement these new authorities to further ensure that stolen, diverted, and counterfeit drugs do not enter the supply chain or are found more quickly if they do.

Next steps

FDA has worked closely with Members of this Committee, your colleagues in the Senate, and other stakeholders to provide technical assistance in response to legislative proposals to secure the downstream pharmaceutical supply chain. Consistent with the position articulated by the President's Intellectual Property Enforcement Coordinator, FDA is focused on establishing an effective track-and-trace system. Broadly speaking, such a system should include:

- A clear path toward implementing an effective track-and-trace system to fully secure the supply chain and enhance protection of public health.
- Enforcement authority to ensure that parties adhere to implementation requirements.
- Requirements for all stakeholders to maintain the distribution history for drugs they handle, unless the system provides a way to verify a drug's authenticity and identify its complete history, when needed.
- Reasonable time frames for implementation based on what is technologically possible and what will result in the best possible outcome for public health.

CONCLUSION

An effective national track-and-trace system for all drug products throughout the supply chain would improve the security and integrity of the drug supply and ensure transparency and accountability of product distribution. Many of the challenges we have with securing the supply chain—including contamination, diversion, counterfeiting, and other adulteration—could be addressed by such a system. We look forward to continuing to work with the Committee to develop a system that meets this promise.

I appreciate the opportunity to testify before you today and would be happy to answer any questions that you may have.

Mr. PITTS. The Chair thanks the gentlelady and we will now have questioning, and I will recognize myself for 5 minutes for that purpose.

Dr. WOODCOCK, if the FDA has a particular concern that a drug could cause an immediate threat to individuals and the sponsor refuses to take action, what would the agency do? Do you believe that the agency's persuasive authority is strong enough that sponsors will take corrective action? Does today's regulatory regime seem adequate given the increase in quantity and sophistication of counterfeiting?

Dr. WOODCOCK. Well, we have authorities to—seizure authorities and other authorities that require judicial actions to do. We also, though, usually will go public with our concerns rapidly and start notifying the health care system. It is uncommon but does happen that firms argue with us over recalling drugs or removing them. It is uncommon but can occur.

Mr. PITTS. Will national uniformity increase the security of the supply chain and improve patient safety? Please explain.

Dr. WOODCOCK. An effective system will help secure the supply chain from the incursions that we have seen that probably are a growing threat over the years by criminals, so that will protect patients and probably prevent harm that we have seen.

Mr. PITTS. Is it important to preserve the States' ability to license and enforce national standards?

Dr. WOODCOCK. Obviously, national standards are useful because of the uniformity because most drugs move across State lines. So I think it is important that both the federal government and the States have the ability to enforce appropriate laws.

Mr. PITTS. Will product serialization increase the security of the supply chain and improve patient safety? Please explain with your answer.

Dr. WOODCOCK. All right. So companies make batches or lots of drugs, OK, and those are large amounts of a same drug. It might be a thousand, it might be a million units would be made. Those are packaged into crates or whatever and sent to distributors, who then send them around the country. At some point those are broken up and then sent to pharmacies and, you know, all around to hospitals and so forth. At that point that's when incursions by counterfeiters can come in if they simply use the same lot number. The criminals are becoming very sophisticated so they can get a few vials of that lot, they can copy the label and put something that is totally fake into the system. So a serialization procedure coupled with some verification at the various levels of distribution would enable us to rapidly identify incursions like that of fake parts of the lot and remove them quickly, and I believe that's why the manufacturers, the pharmaceutical manufacturers, as I think you will hear later today, are moving towards serialization.

Mr. PITTS. Will data exchange and systems between participants in the supply chain increase the security of our drug supply and improve patient safety? Please explain.

Dr. WOODCOCK. Well, I think it is necessary. It gets to what we were talking about earlier about the pedigree. If we don't know the chain of custody of the product, and if we have to reconstruct that later when—say some defective product, dangerous product is

found out there in the hands of a consumer, or worse, they have a side effect which happens, we have to deal with that, and we get a report of serious side effects, then we want to know where did it come from, how many are out there, is it real drug and so forth. And so unless we have that pedigree and we know what hands it moved through, and if we have to reconstruct that later by querying people, that will cause great delays. So if you intend to replace the paper pedigree system, it needs to be replaced by something that has capacity to do that tracking back. So we can rapidly identify other people at risk if we get, say, adverse events or report of a substandard drug, we can rapidly identify where that came from and how it happened.

Right now, we have instances where we get adverse-events report, people die, and we get a large number of reports like this every year for various reasons but some of them might be related to substandard drugs, and we have a very difficult time tracking that back from the patient to the pharmacy and figuring out what the patient actually got. So we would really ask that that pedigree, that whatever is established is at least equivalent in performance to the pedigree we have now.

Mr. PITTS. So finally, would a national track-and-trace standard increase the efficiency of product recalls?

Dr. WOODCOCK. Absolutely. That would be a tremendous tool for us.

Mr. PITTS. Thank you. The Chair now recognizes the ranking member of the subcommittee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Dr. Woodcock, your written testimony lays out a disturbing series of cases illustrating the risk to our drug supply chain posed by counterfeit and stolen or diverted products, and it is not a new problem. We tried to address all the way back in 1987 with the Prescription Drug Marketing Act but for a variety of reasons that didn't work. You described the fact that we need a robust track-and-trace system. I know there are a variety of ways this could potentially be done and the summary of the House discussion draft indicates that it would require lot-level tracing. Other proposals set up a system that would track at a more granular level at the packaging or unit level. You talked about this with questions from the chairman. Can you describe the differences? I mean, I know you basically have described the differences between the two types of systems but tell me the benefits to a unit-level tracking system that cannot be achieved by the lot level.

Dr. WOODCOCK. Right. Well, to reiterate because I think this is sometimes unclear, all right, having a unit-level tracking means that fake units couldn't be put in, and often there are thousands of them that would be made by a counterfeiter right down to the lot number and inserted into the supply chain somewhere and then distributed to patients. By having that verification down at the unit level, we would know that those were extra, those were illegitimate and they could be rapidly identified and removed. And also it would help us, I think, in determining what patients got, what lot they got.

Mr. PALLONE. I mean, it sounds like the lot level would certainly be better nothing but that the gold standard is the unit level, but it seems to me in order to have an effective unit-level system, it

simply has to be an electronic one in which information is exchanged quickly and is available in real time. And I don't think it makes sense over the long term. We would not move beyond a relatively primitive system in which this information is maintained and passed with pieces of paper going back and forth.

So I recognize that creating an electronic system is no small feat, a lot of technology, time, I am sure, investment. But I think we need to ensure that we allow time for an electronic interoperable system be set up. So let me ask you this: do you agree that an electronic interoperable system is ultimately the goal so as long as we allow for enough time to get that kind of a system set up?

Dr. WOODCOCK. I agree, because that would provide the greatest protection for our patients.

Mr. PALLONE. Now, my concern is that the House discussion draft does not even set up the goal of an electronic interoperable unit-level system. It merely requires that the FDA and GAO report back to Congress in 10 years on ways to enhance the safety and security of the pharmaceutical distribution supply chain. If we all agree that our goal should be an electronic interoperable unit-level system, we need to spell that out. We need to require that it be the end game and set a date certain when it must be implemented. Congress can play an important role in driving the technology, and as I said, we need to allow for sufficient time for it to develop and we don't want to set it up with unrealistic expectations, but I think we do need to set requirements or it will never happen. So again, Dr. Woodcock, do you agree that it would be important for Congress to require that this system ultimately be set up?

Dr. WOODCOCK. The goal is ultimately to protect patients and make sure the drug distribution system as drugs are distributed through the system is not porous at different points and has holes or gaps where counterfeits or other things can be inserted. So to reach that goal, ultimately you want to have an electronic system that can identify down to the unit level. However, there obviously are logistic and timing issues, but I think we all mutually share that goal of patient protection.

Mr. PALLONE. But I am just trying to get you to say—I mean, don't you think we should require this at some point, that Congress should require it at some point?

Dr. WOODCOCK. Articulating that goal would certainly probably speed achievement of the desired end, which is to have a system that is capable of preventing these incursions.

Mr. PALLONE. I appreciate that. I mean, look, you know me. I have been around here for a while, and I just can't say there is a phase I and hope for the best. If Congress wants a phase II, I think they should say. Otherwise we are not going to get phase II because inertia unfortunately often characterizes this place unless you spell something out. So I really hope we can work together with our colleagues to improve upon the bill. I think we all share the same goal. We need to better safeguard our Nation's drug supply but we need to make sure whatever legislation we enact actually achieves that goal, it doesn't just give people the hope that someday we will achieve it. That is my concern, Mr. Chairman.

Mr. PITTS. The gentleman's time is expired. The Chair thanks the gentleman and now recognizes the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Mr. CASSIDY. Listen, you explained as well as anybody as I have heard it the need for serialization today so I am going to ask some things to explore, not to challenge. As I gather, California has pushed for a more rapid implementation, but as I gather, they have had to delay this, correct? They have had to delay the implementation of their law. Is that true?

Dr. WOODCOCK. I am not familiar with what California has done. I am sorry.

Mr. CASSIDY. I have learned to say what I have been told, not what I know, but that is what I have been told, which suggests to me that even in a market as large as that that there could be problems with rapid implementation of this serialization.

Dr. WOODCOCK. Well, I think some of your other witnesses may be more familiar with the pragmatic aspects of this.

Mr. CASSIDY. Yes, I think really what is a key here is not the goal which we should go to serialization, it sounds, but the question is, how do you track supply chain, how do you have in one sense an in-the-cloud inventory where someone is not gaming it to figure out that they need to suddenly purchase because it is about to go in shortage. Fair statement?

Dr. WOODCOCK. There is one issue. That is right.

Mr. CASSIDY. And as I gather, those issues have not been entirely worked out?

Dr. WOODCOCK. No.

Mr. CASSIDY. And so putting a date certain that has to be done in a year presumes that they will be worked out within a year but that is clearly not—that is imagining, that is not necessarily knowing that that will occur.

Dr. WOODCOCK. Right. Well, clearly there should be a stepwise approach, but whatever is built now should enable the attainment of the ultimate goal, and there should probably be, as Mr. Pallone was saying, some kind of time frames put so that everyone's mind is focused on the ultimate goal.

Mr. CASSIDY. I accept that. There is nothing like a deadline to sharpen a man's mind. I totally get that. On the other hand, I think we have seen with some things like the exchanges in the Affordable Care Act just putting a date certain doesn't mean that it is going to smoothly happen, and so knowing everyone is impatient to protect patients from criminals, we still have to recognize there are issues to resolve.

Dr. WOODCOCK. Yes.

Mr. CASSIDY. Let me change gears a little bit and talk about drug shortages. You have written a paper. I have had to look over it, the state of the art about the economic factors involved with that, and it seems—no offense—you give a little bit of a short shrift to the role of price competition. Knowing that you know this paper like the back of your hand, in figure two you have a little bubble saying price competition as a factor. But it makes sense to me that if you have declining margins and a 6-month lag so ASP plus six, the provider can only be reimbursed which was the price 6 months ago if it has hit this low point, you can try and raise the price, but

if the provider is only getting paid the lower price from 6 months, she cannot afford to pay for the higher price. Fair statement?

Dr. WOODCOCK. Yes, but I am sure you appreciate, I can't really comment on federal—

Mr. CASSIDY. I understand that, but you can observe that, as your paper does, that lower margins may decrease the ability of a company to invest in manufacturing redundancy, quality, etc. Is that a fair statement?

Dr. WOODCOCK. That is a fair statement, and we feel that there is only competition on price because quality is non-transparent to the buyers.

Mr. CASSIDY. Now, theoretically, though, FDA is going to ensure that there is adequate quality to ensure safety, correct?

Dr. WOODCOCK. That is our job.

Mr. CASSIDY. Yes, it is your job, and so if I am the purchaser, really, as long as I know that it at least meets my minimum standard, why not.

Dr. WOODCOCK. Yes, except—and this is what we try to raise in the paper—there is another aspect to quality, which is reliability, which any of you purchase a car or electronic or anything realize is true, and some of that is reliability of supply.

Mr. CASSIDY. But if you have concentration of manufacturers, you are down to five, six or seven, really, it is not as if you can go someplace else.

Now, let me ask you just in the interest of making this—I understand the numbers of shortages are now down.

Dr. WOODCOCK. Yes, a 50 percent decrease.

Mr. CASSIDY. Are these shortages down because we have actually addressed these issues of lack of redundancy or because we are allowing more foreign product to be introduced?

Dr. WOODCOCK. Primarily because of actions we have taken. We thank the Congress for your leadership in dealing with shortages in the Safety and Innovation Act that was passed last year. We have intervened. We have earlier notification.

Mr. CASSIDY. I got 26 seconds. And so is it from more product coming overseas or is it the ability to work out things domestically?

Dr. WOODCOCK. I don't think the domestic supply has improved.

Mr. CASSIDY. So it is actually more product coming from overseas?

Dr. WOODCOCK. Yes.

Mr. CASSIDY. Let me toss out one thought. I just spoke to a man who has got extensive contacts with foreign pharmacies. He suggests that you put an RSS feed on your Web site. He says that my guys elsewhere have to constantly monitor what is in shortage. They really can't do that. If there is an RSS feed, look, boom, propathol is going on shortage, and it would feed out to them, then they would be able to come to you and solicit. So can our office follow up with you regarding that?

Dr. WOODCOCK. I would be happy to do so.

Mr. CASSIDY. It just seems like a great idea.

Dr. WOODCOCK. Yes, good suggestion.

Mr. CASSIDY. OK. I yield back. Thank you.

Dr. WOODCOCK. Thank you.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the Ranking Member Emeritus, Mr. Dingell, 5 minutes for questions.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy.

Dr. Woodcock, you know that there is a lot to be done here so I will ask that you respond with a yes or no to my questions. Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft and intentional adulteration? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do you agree that a traceability system would help identify and detect illegitimate pharmaceuticals? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers?

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns?

Dr. WOODCOCK. Absolutely.

Mr. DINGELL. It also must be fair, must it not? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. And we have to see to it that it is of course workable?

Dr. WOODCOCK. Right.

Mr. DINGELL. And not impose undue burdens on anybody if we could possibly avoid it? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do you agree that a federal traceability system should include participation from everyone in the supply chain?

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do you agree that a federal traceability system should take a phased-in approach, meaning the first phase would implement lot-level tracing and the second phase would implement unit-level tracing? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. And there are reasons for differences in the different parts of the system for manufacturing and delivering the commodities to the ultimate consumer. Is that right?

Dr. WOODCOCK. That is correct.

Mr. DINGELL. And those make it necessary that we should consider not only the differences but to phase in because of the different levels of difficulty that Food and Drug will confront, right?

Dr. WOODCOCK. Yes.

Mr. DINGELL. Now, do you agree that a federal traceability system with a phased-in approach should include clear requirements and a clear time frame for a second phase? Yes or no.

Dr. WOODCOCK. Yes.

Mr. DINGELL. Do you agree that the goal of any federal traceability system should be unit-level tracking? Yes or no.

Dr. WOODCOCK. Yes, an ultimate goal.

Mr. DINGELL. Ultimate goal but very, very difficult to achieve?

Dr. WOODCOCK. It should be the goal.

Mr. DINGELL. Well, and it will also cause a lot of difficulty to get everybody together on this.

Dr. WOODCOCK. Absolutely, because there are tradeoffs here.

Mr. DINGELL. Do you agree that traceability legislation should avoid placing undue burdens on FDA so that the FDA can focus on proper and efficient implementation of this particular program and all of the others which we have been loading Food and Drug down with lately?

Dr. WOODCOCK. Yes.

Mr. DINGELL. And with which we have not been giving you enough money? You may not want to comment on that, but that is my feeling.

Dr. WOODCOCK. It is difficult. We try our best.

Mr. DINGELL. I know you do, and it is an enormously difficult task. Do you believe that the traceability legislation should ensure adequate systems are in place to trace prescription drugs before current pedigree requirements are eliminated? Yes or no.

Dr. WOODCOCK. Absolutely.

Mr. DINGELL. Now, this traceability system and the phase related to it must also focus very carefully upon imports. Is that right?

Dr. WOODCOCK. Yes.

Mr. DINGELL. Particularly imports that are components of pharmaceuticals ala the situation which we had with heparin but other examples of this, and of course, as a matter of fact, also with regard to food and other things that you have to contend with. Is that right?

Dr. WOODCOCK. Yes. Well, I think the components of drugs is different, and the supply chain issue is different than the distribution chain but equally important to keep substandard ingredients out.

Mr. DINGELL. And I am not here to sell foods at this particular time but we have to look at that and other things too.

Now, Doctor, do you agree that traceability legislation should provide FDA with adequate enforcement authority to ensure stakeholders comply with the intent of Congress? Yes or no.

Dr. WOODCOCK. Yes. Can I say, we don't want to be a paper tiger on this?

Mr. DINGELL. I sure don't want that. It is also fair to observe that Food and Drug has been working very carefully with Members of Congress, House and Senate, Democrats and Republicans, but also that you have been working with the industry to try and see that we get something with which everyone can work and to do so comfortably. Is that right?

Dr. WOODCOCK. That is correct.

Mr. DINGELL. And of course, that would be the goal of Food and Drug, as it would be of everybody, I think, in this room.

Mr. Chairman, I return 19 minutes. Thank you.

Mr. PITTS. Seconds. Thank you.

Mr. DINGELL. Nineteen seconds.

Mr. PITTS. The Chair now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Dr. Woodcock, welcome. Glad to have you back.

Dr. WOODCOCK. Thank you.

Mr. SHIMKUS. I am going to do a kind of intro and then go to my specific question on a specific item.

We have seen many instances in recent years of how technology can help us modernize and create efficiencies in communications, and I am referring to stuff that we moved, actually signed by the President in my other subcommittee, which is a hazardous-waste issue, and we were able to through legislation kind of relieve the burden of paper copies throughout the supply chain all the way to the fact when the President signed the law, and we know in the old days carbon copies, triplicate papers, they are stored throughout the entire chain, that can be costly. We also have recently seen where the EPA has on their own with some prodding from us now is able to notify water users—the water plants can notify the users of the water on changes based upon email notifications versus mailing paper copies of changes and the like.

So that leads me to this whole debate that Ranking Member Pallone is also very interested in, the e-labeling requirements reflected. There are some reflected in this discussion draft with more standardized electronic approach that will increase, we believe, patient safety and provide significant quality improvements and cost reductions to patients and industry. This is something that, as I mentioned, that we have been following, and Ranking Member Pallone has also been leading on this. Do you support this e-labeling policy?

Dr. WOODCOCK. I have long supported this. We have worked with the National Library of Medicine. We have something called Daily Med, and Daily Med has, I think, 24-hour update so at the National Library of Medicine you can get any drug label, the actual on-time, real-time label with any safety updates within a day of FDA changing that label. So that should enable easy electronic access from almost anywhere.

Mr. SHIMKUS. So with respect to this proposed legislation and what the bipartisan members are trying to work out, there is obviously some language that deals with this. I guess we would be concerned as to where are you at as an agency in issuing guidance and moving forward on your own?

Dr. WOODCOCK. My understanding is, this requires rulemaking. The fact is that we are planning to issue a rule is on our agenda, and we plan to issue a rule this year, we would hope, a proposed rule.

Mr. SHIMKUS. So I guess from the cosponsor of the legislation and the committee and ranking member would have to look and see the time, your time frame as rulemaking sometimes takes a long time and a decision made of whether we want to add that in legislative language, but you are really supportive of the overall process and principles, it seems like.

Dr. WOODCOCK. For drugs, all the pieces of this are in place so there is a labeling repository. We do all our reviews electronic at the agency at CDER and so everything is in place to enable electronic access from anywhere to the real-time drug label.

Mr. SHIMKUS. And the real-time drug labeling is the key because things can change pretty rapidly, and you can get it electronically versus something stuffed in a box that gets transmitted forward. So I appreciate your response and I appreciate you being here, and Mr. Chairman, I yield back my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. Track-and-trace is an important issue, and I want to thank my colleague and neighbor, Representative Matheson, for his leadership on our side on this issue. Finding bipartisan agreement on any issue is difficult, and on more complex issues, such as supply chain for pharmaceuticals, remains even more elusive. However, I do have some concerns about the Latta-Matheson. Most importantly, the bill never really gets us to an interoperable electronic unit-level system. In fact, it prohibits FDA from moving ahead with interoperable electronic system in absence of new legislation, which we won't on until 10 years after the enactment. I understand the concerns that market participants have problems moving too fast toward such a system. We should be sensitive to this and make sure the law we pass is workable. But we have an opportunity to move the ball further down the field, and it my understanding that quite a bit of necessary technology already exists. Pharmaceutical companies, large and small, have stated they can work on a shorter timetable. We can do more to ensure the safety and security of our drug supply, and I think we should. But instead of moving toward requiring an enhanced system, the bill only requires the FDA to conduct one or more pilot projects and conduct public hearings and report back to Congress on the result within 10 years. I am concerned that these pilot projects do not seem to be designed to test the electronic interoperable unit-level system that everyone seems to agree we need.

My question is, if the goal is to get to an electronic interoperable unit-level system, which I thought was based on last fall's draft with indeed a shared goal, wouldn't it make sense for the legislation to explicitly direct the FDA to conduct the pilot program, testing out whether such a system could be established, and instead of just mentioning in vague language about better securing the supply chain. Would you like more definitive black-letter law and guidance instead of come back to us every 6 months and in 10 months from now we might get to this?

Dr. WOODCOCK. As I said earlier, I think within the standards world where people are being asked to conform to a standard over time and they have to change processes, they have to make investments to do that, clarity is critical and predictability so that people know what is going to happen and they can plan for it and plan their investments, plan their programs. So I think to the extent that there is a shared goal that Congress can provide clarity on where we are going as a country and where we plan to end up, that would be beneficial to all the stakeholders, even those who feel right now that this is a tremendous burden to provide clarity of a path would be extremely helpful.

Mr. GREEN. And we authorize legislation and sometimes Congress doesn't reauthorize, we just kick the can down the road, and telecom is a great issue. The 1996 Telecom Act, I think it was outdated when we passed it but it is well outdated now. So my worry is that we won't continue to oversee it.

My next question is my concern about, it requires the FDA to conduct a public hearing every 6 months until FDA submits a report to Congress, which could be up to 10 years from enactment.

Transparency is important. I agree that open and public hearings of these issues with interested stakeholders makes sense, but twice a year for 10 years seems like it is a little much. Can you talk about all that is involved in setting up a public meeting? Do you have any sense how much these meetings may cost over the 10 years twice a year for 10 years?

Dr. WOODCOCK. These meetings often cost, maybe up to \$20,000, depending on how they are structured, but I think the opportunity cost is the cost we are really talking about here. Don't forget, we are trying to work with patient groups, and they are extremely excited about having meetings about their disease and how we can better study it, and under PDUFA that you all passed, we agreed to have 20 of these meetings over the next 5 years. Now, we would like to have more. We have heard from so many patient groups that they aren't maybe on the list and they are really concerned about their disease. So it is really important. We also have pediatrics and how we develop drugs in children. We have many other pressing issues that have immediate impact on patients that we need to have various public meetings on. So there is a tremendous opportunity cost there if we are having—if we meet on a certain subject excessively.

Mr. GREEN. I only have about 30 seconds left, and I would like to match our chairman emeritus in giving time back. I think the bill is a good step, but I don't think it goes far enough and it fails to give us an interoperable electronic unit-level system before 10 years, and frankly, I think industry may be ready much earlier than that, and we don't want to tie our hands where we can't do it.

So Mr. Chairman, I appreciate the hearing today and hopefully we will provide some more flexibility. Thank you, and I yield back my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Dr. Woodcock, I appreciate you being here today, and I have heard a number of folks say this is not an issue where there is one side or the other, and that is true. I do have some concerns.

I represent a very rural district, and we have a lot of community pharmacists tucked in various nooks and crannies of my community. That being said, people are used to going to those pharmacies. They like those pharmacies. And I am just wondering as we go forward, you know, these folks have a lot of competing issues that they are facing already from other issues. As we go forward in looking at this, while we all want to make sure our supply chain is safe, can you describe what efforts the FDA has taken into account to accommodate and incorporate the small community pharmacies and make sure that they are not overly burdened by any system that we put into place?

Dr. WOODCOCK. Well, we talked to all stakeholders about this. As I said earlier, developing standards and implementing that in a stepwise way is probably the best approach to not impacting small entities excessively so they know what is coming and they can plan for it over time, and if Congress were to establish that plan, then vendors will come in and develop solutions over time and they can

be adopted somewhat earlier by a larger chain, say, and would be affordable for smaller groups.

So I think we need to—if Congress decides to put forth a plan, I think that would be very helpful in having everyone understand where we are going and then getting the power of commerce and entrepreneurialism and invention to develop the technologies that will make this or actually craft these technologies to this situation in a way that will make it affordable.

Mr. GRIFFITH. Well, I have to say that makes sense to me. If you give people time to respond and to figure things out and there is enough time to come up with new ways of doing things, I do believe that vendors will come forward. Of course, the key is, as I have heard from some folks, they want to do things faster, and we have to find that sweet spot, which is why we have draft language to talk about as opposed to an actual bill at this point. But I do appreciate the sponsors who brought it forward for us to at least have something to work on, and I appreciate you being here today.

You also mentioned in your testimony a track-and-trace public workshop held in February of 2011. Can you just speak generally about feedback you received, and keeping in mind my community pharmacies that are a big concern? It is not that I don't care about the big chains but they are in a much better position to adapt quickly to the changes that may be coming.

Dr. WOODCOCK. We understand the concerns of the community pharmacists, and there testimony today that I read that was submitted and last year also, so we understand and certainly we have talked to that community and heard at our public meeting about these concerns—logistical concerns, time concerns, the fact that they feel stressed already between various demands on them. There is other competition. But it is really important in these rural communities to have a pharmacy there. So we understand all that, and I guess what I am saying is that putting in the goal and predictability over a time frame I think would be very helpful for everyone because they get their mind around what is going to happen in the future.

Mr. GRIFFITH. Yes, ma'am. I appreciate that. It makes sense to me as well.

Mr. Chairman, with that, unless somebody wants my time, I will yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentlelady from Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and I look forward to this discussion because I have a specific issue that I wanted to discuss, and of course, the issue of altered, counterfeit, substandard or tampered-with medicines entering the drug supply is a real concern and it is a very important issue for FDA and this subcommittee to address, but I want to raise a consequence that may or may not be intended but it is not warranted, and I hope that the proposed legislation can help or that there is something that FDA can do about it.

In the efforts to keep substandard drugs out of the U.S. marketplace, re-importation from a foreign jurisdiction is prohibited. The U.S. Virgin Islands, as the name indicates, is a part of the United

States. Our pharmacists are U.S. trained. They have U.S. licenses. Our pharmacies are regulated by U.S. law, and our pharmacies including our hospitals only order medication from U.S. distributors. As a provision of the treaty that was signed when the United States bought the Virgin Islands, we are outside of the U.S. custom zone so for shipping only we are international. Again, we are totally domestic except for shipping, and because of that, our pharmacies have been unable to ship back their medication that might have been oversupplied, spoiled, expired. They are unable to ship it back to their supplier, and it incurs costs and those costs are passed on to the patients. So we have met on this in the past in the past Administration. I have legislation to try to address it. But we are willing to work on anything that can be worked on and maybe, you know, we want to work with our colleagues on the committee but maybe there is something that FDA would be able to do.

So if this national track-and-trace system in place, would that be a way to help us fix that, do you think?

Dr. WOODCOCK. Probably, but I can't opine on the legal aspects because it would require analysis. You raised this issue with me last year, and we agreed that your staff would talk to our folks, and I had thought this had been resolved or improved. So I would also urge you to talk to FDA staff again and raise this issue. We can follow up with you. But I do believe obviously things can be put into legislation that would remedy a situation like this as well.

Mrs. CHRISTENSEN. But you would not oppose it, would it, if we were—

Dr. WOODCOCK. No, I think—

Mrs. CHRISTENSEN [continuing]. Only shipping back to the distributor?

Dr. WOODCOCK. Well, a track-and-trace system would actually enable this because we would know what the drugs were.

Mrs. CHRISTENSEN. And I thought it was resolved also. They were shipping by FedEx and it wasn't being checked but now it is back to square one. So thank you very much, and I don't have any further questions, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you, Dr. Woodcock, for being here today.

I have a couple of questions on the basically moving towards the electronic access for, you know, data for patients, which now of course are the package inserts that accompany medication. I do believe that the real-time access is very, very important but I am concerned about our seniors and their ability to have that information right there for them. I have heard from many seniors who—as a nurse, I know how important it is for them to have that information. So what exactly is the push there? I mean, I understand the technology, the ability to access it online is very important, but there again, many of our seniors are not Internet savvy, and I am concerned that maybe we are moving a little quickly with this. So what are your thoughts on that?

Dr. WOODCOCK. Well, what we are talking about is package inserts, and many physicians have trouble with the package insert.

Mrs. ELLMERS. Well, it is a lot of information.

Dr. WOODCOCK. Yes, so we are also working an initiative we call Patient Medication Information, all right, and we have been working on that for some time, and we are about the only country in the world that doesn't give patients a leaflet about their drug in patient language. So we are moving to do that, and it would be a combination of electronic and paper, depending on what the individual desired.

Mrs. ELLMERS. OK.

Dr. WOODCOCK. Yes. And it would be one page probably with access to more if people wanted more information or instructions on how to get more information.

Mrs. ELLMERS. So that wouldn't automatically come with the medication is what you are saying?

Dr. WOODCOCK. It would.

Mrs. ELLMERS. It would automatically come?

Dr. WOODCOCK. Yes.

Mrs. ELLMERS. Because I am thinking a combination approach is definitely the way—

Dr. WOODCOCK. For consumers.

Mrs. ELLMERS [continuing]. That we should go, and, you know, certainly, again, the package inserts do come with more than enough information obviously for different reasons. So you do favor more of a combination approach?

Dr. WOODCOCK. For the patient.

Mrs. ELLMERS. For the patient?

Dr. WOODCOCK. That is right. We feel that people who prescribe drugs or dispense them, all of them are going to have electronic access.

Mrs. ELLMERS. Right, and availability. So the electronic access is more for the physicians?

Dr. WOODCOCK. Technical.

Mrs. ELLMERS. OK. Thank you for clarifying that for me because that was definitely an area I was very concerned about.

Now, I do want to talk a little bit about—oh, I only have a few moments. But the track-and-trace as far as, how do you basically figure out which things would be tracked and traced based on drugs and based on other things like saline or additives, things that mix drugs? I mean, will that also be included in track-and-trace?

Dr. WOODCOCK. They are drugs, so obviously whatever is included is up to Congress, but we would feel that anything that goes into a drug should be. So we regulate saline bags and so forth as pharmaceuticals now. They have their own code, they have lot numbers and so forth, and often we have to recall those.

Mrs. ELLMERS. OK. So you are looking at anything that is considered a drug?

Dr. WOODCOCK. Yes.

Mrs. ELLMERS. Thank you very much.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the Ranking Member of the Full Committee, Mr. Waxman, for 5 minutes for questions.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Woodcock, as you know, California has a law that once completely implemented will require that all transfers of ownership of prescription drugs from the manufacturer through to the final pharmacy dispenser be accompanied by a so-called pedigree that maintains a record of each successive transfer and tracks information about the drug product at the unit or package level. Under the law, these pedigrees must be transferred electronically and the entire system will have to be interoperable so that all the information on any prescription drug will be readable and updatable by all members of the drug distribution chain. This law is quite comprehensive and ambitious and has been the subject of criticism by some industry members as being too ambitious, either in its scope or its time frame for implementation.

But I was glad to hear on your answers to Mr. Pallone's questions that you agree that an electronic interoperable unit-level system should be the goal here. I agree that we need to allow enough time for the technology to evolve and for the system to be put in place. We don't want to set unrealistic expectations. But I think California had it right when they insisted upon this kind of system, and I think this system is ultimately the right one for the country.

As Mr. Pallone mentioned, the Latta-Matheson draft doesn't even set this up as a goal even at some distant point in the future, to create an electronic interoperable unit system. In fact, they prohibit FDA from moving forward with this kind of system ever. I think that is the wrong policy. The Latta-Matheson bill also doesn't require any kind of tracing of drugs until 5 years after enactment at the earliest. But perhaps even more concerning to me is that on day one, as soon as this bill would be passed, it would preempt State law even though they never created an effective alternative at the federal level. On day one, all State laws on the subject are wiped out, and to be clear, this is not just California's law. According to the Health Care Distribution Management Association, at least 11 States have laws requiring distributor licensing and pedigree requirements. Some States like Florida have a requirement that a pedigree be passed with most drug transactions, and you mentioned this in your testimony, but last year Representative Cummings and Senator Rockefeller issued a report detailing their investigations of the gray market in drug trade in the United States and some of the dangers it poses, and they discussed the importance of pedigrees for law enforcement in these cases. But the very law requiring these pedigrees would be erased under the House's bill on day one.

Again, you mentioned this in your testimony but I would like to hear more. Can you tell us whether you think preempting these State laws on day one makes sense when we never get to the system you say we need? Please explain in more detail what would be the consequence of wiping out currently existing pedigree requirements? I am deeply concerned about preempting not only California's law but the other States' laws that clearly provide a benefit today, I agree that if we can't get to a strong federal system, it might make sense to preempt State laws. But the Latta-Matheson draft certainly does not create a system worthy of broad preemption on day one. Would you elaborate on this?

Dr. WOODCOCK. I think it is really important that whatever is enacted does not lower the safety of the drug supply, doesn't decrease or put bigger holes in the safety net. That is really important. So the pedigree requirements now, as I said——

Mr. WAXMAN. Just for clarification, safety net——

Dr. WOODCOCK. Of tracking.

Mr. WAXMAN. We are not talking about poor people. That is usually what——

Dr. WOODCOCK. Oh, I see. OK. Maybe I used the wrong term. But the safety around drugs, of the drug supply, OK? Eliminating the paper pedigree until we have something else in place would be creating greater loopholes for insertion of counterfeit drugs and substandard drugs into the distribution chain because we wouldn't be able to track them backwards, all right? And putting a law in place that eliminated States' ability to require that tracking without providing something comparable in its place would be lowering the safety of the drug supply for whatever time it took.

Mr. WAXMAN. I agree. Let me ask you one other question in the few seconds I have. California law also ensures that all entities in the supply chain participate in the e-pedigree system. One of the major issues we have confronted in the context of this debate is whether pharmacies should be required to be part of the system. Do you think it makes sense to exempt pharmacies from a nationwide track-and-trace system?

Dr. WOODCOCK. I think ultimately if we want to know what drug the patient got, OK, and several times in the last several years that has been imperative for us to figure out what drug each patient got because sometimes we hear about the problem from the patient dying——

Mr. WAXMAN. So you think the pharmacies should be included so we know what the patient got?

Dr. WOODCOCK. Eventually, that is the only way to know what the patient got, and so we end up doing these elaborate investigations to figure out which drug the patient got, and yet often, as I said, we can't pull the drugs out of the patient's hands because they may be lifesaving medicines. So we may in the next several years get into a tragic situation because of that. So I think the ultimate goal really ought to be our ability to track down to that level.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Dr. Woodcock, great to have you back here. I always appreciate your candid testimony.

This may have been asked before, and I apologize if I am asking it again, but I would like to know. So how are things done now? How are you made aware that if there is a problem with something that may be counterfeit, toxic, contaminated, what is the process now by which we find out?

Dr. WOODCOCK. Well, there are a whole variety. We may be alerted from the health care system. They may find it and they look at it and they see something is wrong. We may be alerted by whistleblowers who see, you know, this drug's label is in Turkish, this can't be right, OK? We may—and the ones that we are very

concerned about is where we get harm, patient harm, and so we get adverse-event reports, people are dying and we don't know why, and then we have to go out and do a huge investigation of what did they get and so forth.

Mr. MURPHY. So right now it is towards the end of the supply chain that you may find something by an adverse event or someone—

Dr. WOODCOCK. Yes, and we feel with the law that was passed last year, now manufacturers have to tell us if they get a component that is falsified or substandard, they need to tell us that now, but out in the world, usually it is sort of voluntary. Pharmacists will call us, a nurse or whatever, and we will find out about it that way.

Mr. MURPHY. And this may be at the end of things. What about in terms of the ingredients that go into these? Do you pick up anything on that too, or is that the manufacturers on their site testing the quality of their ingredients?

Dr. WOODCOCK. We ask them to test, and as I said, the Innovation and Safety Act included additional provisions on the supply side, the incoming side to make a drug, to strengthen that, making them strengthen their controls on the supply chain and the testing and so forth when they receive the components.

Mr. MURPHY. So now if the FDA has a particular concern about a drug that would cause an immediate threat to individuals, what would the agency do?

Dr. WOODCOCK. We talk to the company and ask them to do a recall or they may have instituted a recall themselves. We do a risk assessment, which we call Health Hazard Evaluation, and we determine the level of possible harm, and if it is a class I recall, then we have to decide should it go down to the patient level and be pulled out of the hands of the patients and then we do—the company is supposed to be in charge of that but we audit that, the effectiveness, to make sure it is happening, and if it is a really bad problem, we may collaborate with the CDC or the public health departments in the States, you know, to make sure this all happens.

Mr. MURPHY. OK. Let me ask something. A witness on our second panel, Walter Berghahn, notes in his testimony there has been “a tremendous amount of effort expended in the last 10 years to tighten up and secure the supply chain. Those efforts certainly have closed many of the cracks and yet counterfeits still appear, and the FDA has opened more investigations in the last few years than ever before, more than 70 instances in 2010 alone.” What do you attribute to these increased investigations? Is it that the FDA is getting better at it or the problem is getting worse?

Dr. WOODCOCK. Always hard to know, right? I think the problem is getting worse. We know from our colleagues around the world that in some parts of the world, 50 percent of the drug supply is counterfeit, but those folks in that part of the world don't pay a lot for their drugs, so our market is ideal because the drugs are expensive and you get a lot of money for them. And so we see more professional criminals getting involved, racketeering, very high-level criminal elements, conspiring to do this and penetrate the U.S. drug supply because there is a lot of money to be made.

Mr. MURPHY. We hear a lot about people who offer drugs online. Your recommendations on whether or not people should purchase anything when they go to a Web site and they say, oh, here is my prescription, I will just get it from there, your recommendation is should they or should they not purchase from those?

Dr. WOODCOCK. There is a program called VIPPS, which offers certified online pharmacies. Certainly some of the pharmacies are fine. Many of them, we have looked, we have ordered, we have done this. You can get counterfeit drugs very easily or substandard drugs ordering from an online pharmacy that you don't know anything about.

Mr. MURPHY. So make sure you know who that online pharmacy is. Finally, let me ask you this, and this relates to what I was just asking about too. Could this legislation eventually lead to less drug shortages or more because you are watching more closely? What do you think the outcome will be?

Dr. WOODCOCK. I don't think it will have a huge impact on drug shortages, frankly. I think that problem, as we discussed earlier, has other root causes other than—obviously the existence of shortages is another temptation for people to introduce counterfeit because people are desperate to get these medicines and they will pay a lot for them. But I don't think that is the root cause of shortages.

Mr. MURPHY. Thank you very much. Yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentlelady from Florida, Ms. Castor, for 5 minutes for questions.

Ms. CASTOR. Thank you, Mr. Chairman, and I want to thank my colleague, Congressman Matheson, for bringing the discussion draft to us, and welcome.

Dr. WOODCOCK. Thank you.

Ms. CASTOR. Dr. Woodcock, a critical part of an effective drug supply chain is the ability to secure a stable supply of medically necessary drugs, and I know this isn't a hearing on drug shortages but there is a very serious issue and I feel compelled to ask you about it, and that is the critical shortages involved with babies in the NICUs right now, the neonatal intensive care units in children's hospitals in NICUs all across the country. We are talking about the calcium, zinc trace elements, magnesium. I have been advised by some children's hospitals that they have less than 2 weeks of nutrients left, and this is already impacting their ability to provide the top standard of care for the most vulnerable of patients. I do understand that you have been very aggressive in tackling this problem along with your drug shortage professional staff, the children's hospitals and the manufacturers, but it is so serious now that a medical director at one children's hospital is calling it the worst crisis he has ever seen in 30 years. What is happening on this now and what is the outlook here over the coming months?

Dr. WOODCOCK. Well, we have worked with one manufacturer to allow them to ship product along with filters to filter out the product that is precipitating, because you can't give particles in IV fluids. It can embolize into the lungs. So that should provide some of the products. We are also working with manufacturers outside the United States to make sure their product is OK and bring it into the country. We recognize this is a critical issue and it is

reaching a critical stage, and we need to get product out there for these babies. We understand that.

Ms. CASTOR. So what is your time frame? Because they are saying they only have the product for the remaining 2 weeks, and what is happening is there are professionals are calling all over the country trying to find the elements that they need. Are they going to be able to see some relief here over the next week or two?

Dr. WOODCOCK. We hope so. As I said, some of these products are being shipped now with filters, all right, then others we negotiating on importing some of those other elements into the country, and once we can give the green light that we are assured of the safety, then they can be made available pretty rapidly.

Ms. CASTOR. OK. That is the short-term solution. What is the longer-term answer?

Dr. WOODCOCK. The long-term solution appears to be some structural problems, as we talked about earlier, in how these drugs are manufactured and delivered to patients and the lack of a robust supply. So if one manufacturer goes down in the United States, they may be the sole source of some of these life-maintaining products, and that is a really bad situation. It is sort of outside of the scope of FDA, though, to figure out how to have more manufacturers.

Ms. CASTOR. And drug shortages in general, have you noticed a ramp-up in counterfeits that try to fill that void in the market over the past few years?

Dr. WOODCOCK. In some cases people, unscrupulous people, exploit the existence of a shortage to try to introduce substandard products.

Ms. CASTOR. Which particular areas have you seen that?

Dr. WOODCOCK. We would have to get back to you on that as far as all the details.

Ms. CASTOR. OK. Thank you very much. I yield back.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the gentleman from Utah, Mr. Matheson, 5 minutes for questions.

Mr. MATHESON. Well, thank you, Mr. Chairman. You know, this is an issue that a lot of us have been working on for a number of years, and I want to acknowledge some of the colleagues, Congressman Boulter and Congressman Bilbray, who both worked on this issue, and then I am pleased to be working with Mr. Latta. And I think this year we have an opportunity to really get something done, and I think we should all embrace that opportunity to try to work together. We put out a discussion draft. This is not a bill. It is an opportunity for us to really start to dig into this issue and have a substantive discussion, and I hope that is what we do, and this hearing is the first good step in that process.

And I really want to thank Dr. Woodcock, who has spent a lot of time on this issue, has been very open, has talked to me on the phone about this issue before and been engaged for a long time on it, and I know you have a strong desire to come up with a national standard that sets the rules for everybody. I think there is a need for preemption. I heard some questions earlier concerned about timing of preemption but I think we all know we need one set of rules in this country and not 50 different State rules, and I think you would acknowledge that, but I do appreciate all you have done.

You put your own time in and your staff in offering resources on this.

In your testimony, you describe several situations or instances of counterfeit drugs finding their way into the supply chain. Many have been reported in the press reports. Can you describe for us how the product was able to really get in the supply chain, and you can talk about the emerging level of sophistication that the bad actors are deploying right now to do this?

Mr. WOODCOCK. Yes. We see a range of sophistication, and of course, the ones we are most worried about are those who are actually able to copy, really make a counterfeit. It looks like the authentic product. It has the label of the authentic product and yet it isn't. It may often have nothing in there, or we have had that had regular water, which is very dangerous to just give to people, say, intravenously. So they are introduced at some point in the distribution chain. It may be a secondary distributor level. It may be the pharmacy level. It may be somewhere in between there. It may be where something is shipped to a clinic and they buy from a distributor who actually probably due to perhaps the amount of oversight that we should have of some these licensed distributors, they are sort of the launderers. They launder these products and then put them into a legitimate chain, send them out to, say, cancer clinics and then people use those drugs that are not effective.

Mr. MATHESON. And it is safe to say with over a \$300 billion annual prescription drug market in the United States, this is pretty attractive.

Dr. WOODCOCK. That is right.

Mr. MATHESON. The reason I ask this, I know this sounds obvious to everybody but this is why we are doing this. I mean, our current system is not necessarily structured where it can best mitigate this challenge of counterfeiters, and I think there are a lot of important issues, a lot of important details in this discussion draft, but I think it is important we all acknowledge why we need a national standard, why we have to do something better than we have now because the bad guys are getting smarter, more aggressive and there is just too much money on the table for them not to want to do some bad things.

One other question, and then I will let you go. You touched on this a little perhaps in other questions but can you walk us through how moving forward with a robust track-and-trace system would complement the work that this committee undertook last year in the latest version of PDUFA, how that is going to complement what that bill already gave you some authority to do?

Dr. WOODCOCK. Absolutely. There are two sides to the whole chain of medicines. One is the supply chain where you get all the components, maybe the IV bags, the active pharmaceutical ingredient and all other components. They go into the manufacturer. That is one area where the Innovation and Safety Act really addressed that supply chain and tightened up some big loopholes that existed. Now this is a distribution chain, OK, the manufacturer makes the product, but then as I described, they send it out all over through a chain of distributors and so forth down to the pharmacy or clinic or hospital level, and that is the chain where there are big loopholes still where these fake products can be inserted or

we just don't know where the products are going, and so once we have an approach and a goal laid out for this distribution chain side, then we will have a very intact system that we can have much more confidence in.

Mr. MATHESON. Thanks. Mr. Chairman, I yield back.

Mr. PITTS. The chair thanks the gentleman. That concludes the questions from the members. I am sure they will have some follow-up questions, some other questions. We will send those and ask that you please promptly.

Dr. WOODCOCK. We will be delighted to work with you.

Mr. PITTS. Thank you very much, Dr. Woodcock, for your testimony.

That concludes the first panel. We will ask the staff to set up for the second panel. We have seven witnesses. We will take a 2-minute break while they set up.

[Recess.]

Mr. PITTS. The Subcommittee will reconvene. On our second panel today, we have seven witnesses, and I will introduce them in order of their presentations. First, Ms. Elizabeth Gallenagh, Vice President of Government Affairs and General Counsel, Healthcare Distribution Management Association. Then Ms. Christine Simon, Senior Vice President of Policy and strategic Alliances, Generic Pharmaceutical Association. Mr. Michael Rose, Vice President of Supply Chain Management, Johnson and Johnson Health Care Systems. Dr. Tim Davis, owner, Beaver Healthmart Pharmacy on behalf of the National Community Pharmacists Association. Mr. Allan Coukell, Director of the Medical Programs of the Pew Charitable Trust. Dr. Carmen Catizone, Executive Director, National Association of Boards of Pharmacy. And finally, Mr. Walter Berghahn, President of Smarter Meds for Life and Executive Director of the Healthcare Compliance Packaging Council.

Thank you all for coming. You will each be given 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Ms. Gallenagh, we will start with you. You are recognized for 5 minutes.

STATEMENTS OF ELIZABETH GALLENAGH, J.D., VICE PRESIDENT OF GOVERNMENT AFFAIRS AND GENERAL COUNSEL, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION; CHRISTINE M. SIMMON, SENIOR VICE PRESIDENT, POLICY AND STRATEGIC ALLIANCES, GENERIC PHARMACEUTICAL ASSOCIATION; MICHAEL ROSE, VICE PRESIDENT, SUPPLY CHAIN VISIBILITY, JOHNSON AND JOHNSON HEALTH CARE SYSTEMS, INC.; TIM DAVIS, R.PH., BEAVER HEALTH MART PHARMACY, ON BEHALF OF NATIONAL COMMUNITY PHARMACISTS; ALLAN COUKELL, DEPUTY DIRECTOR, MEDICAL PROGRAMS, THE PEW CHARITABLE TRUSTS; CARMEN A. CATIZONE, R.PH., D.PH; AND WALTER BERGHAHN, EXECUTIVE DIRECTOR, HEALTH CARE COMPLIANCE PACKAGING COUNCIL

STATEMENT OF ELIZABETH GALLENAGH

Ms. GALLENAGH. Good morning, Chairman Pitts, Ranking Member Pallone and members of the subcommittee. I am Liz Gallenagh, Vice President, Government Affairs, and General Counsel at HDMA. Thank you for this opportunity to inform you about the critically important issue of prescription drug pedigree, traceability and supply chain safety. I would also like to thank Chairman Upton, Congressman Latta and Congressman Matheson for their leadership in this area as well as the hard work and dedication of their staff.

The pharmaceutical distribution industry's primary mission is to operate the safest, most secure and efficient supply chain in the world. As part of this mission, HDMA's members work to eliminate counterfeit and diverted medicines by capitalizing on the technological innovation and constant improvements in efficiency that are the foundation of our industry.

Today, on behalf of our 33 members, I am here to express HDMA's strong support for a national, uniform approach to pedigree and the traceability of medicines throughout the supply chain. I will speak with more detail later in my testimony, but I want to state that we support the core elements of the Latta-Matheson proposal and look forward to working with you and your Senate colleagues on the final bill.

HDMA believes that any reform and modernization of the supply chain should raise national wholesaler standards and include a new federal ceiling for pedigree and traceability requirements to improve safety and uniform and establish the foundation for longer-term electronic solutions such as unit-level serialization and product tracing. In addition to fundamentally addressing counterfeit and diverted medicines, a national approach may be a useful tool in discouraging gray market activities associated with drug products in short supply. More importantly, it will put the United States on par with other countries around the world that are currently beginning to engage in serialization and traceability efforts.

After many years of debate, it appears that we finally may have an opportunity to enact federal legislation in this area. This is in large part due to a broad consensus among supply chain partners as well as growing support from Members of Congress. While Congress, FDA, and industry have been working at this diligently for

several years, it is critical that Congress act now due to the uncertainties faced by the industry, the need for uniformity across the supply chain, and to ensure patient safety.

Basic guidelines for pedigree were set forth 25 years ago with the enactment of the federal PDMA. Since that time, activity at the State level has varied with some enacting very complex laws and others never going further than the original guidelines. Based on our experience, the complexities of dealing with multiple approaches in the States will only get worse if we fail to solve this problem now at the national level.

Since Florida's first foray into raising pedigree and licensure standards in 2003, we have seen dramatic variations across the country. This variation has occurred despite HDMA's attempts to work in every State along with fellow stakeholders to achieve more uniformity. Today, for example, 29 States have acted beyond the federal PDMA standards. The States of Florida and California are viewed as leaders in this area. However, they take completely different approaches, California being the most complex and forward-looking with track-and-trace and electronic pedigree implementation beginning in 2015, and Florida being the most stringent today in terms of what is happening in the supply chain with pedigree requirements.

This patchwork not only creates operational challenges but also leaves openings for bad actors shopping for more lenient State rules, openings that could mean the difference between a fake or diverted medicine being dispensed to an innocent patient in need of important treatment. Because of this State-by-State variation, we believe pedigree and traceability should be under the purview of Congress and the FDA.

We have been a leader in this field and we are dedicated to working with supply chain partners and stakeholders on a consensus approach to pharmaceutical traceability. We are an active member also of PDSA, the Pharmaceutical Distribution Security Alliance.

The bipartisan discussion draft released by the committee this week achieves these goals and captures the core consensus elements that will significantly improve the integrity and safety of the supply chain. Specifically, the proposal does include national requirements for wholesaler licensing while preserving a critically important role for the States; uniform direct purchase and standard pedigree options; eliminating the current 50-State patchwork, manufacturer serialization at the unit level and case level, enabling unique identification of prescription drug products for the first time in the United States; the development of electronic systems and processes to facilitate traceability and transaction data exchange to provide additional efficiency and safety benefits within the supply chain, and appropriate transition times and development phases for the migration to traceability for each segment.

There is no single element that will protect the supply chain from every threat but rather a comprehensive solution should incorporate each of these elements. We applaud your work and urge the committee to advance this important issue this year. Now is the time for Congress to act to bring cohesion and consistency to our national drug supply chain.

[The prepared statement of Ms. Gallenagh follows:]

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

**Testimony before the
House Energy and Commerce Committee
Subcommittee on Health
United States House of Representatives**

April 25, 2013

**Elizabeth A. Gallenagh
Vice President, Government Affairs and General Counsel
Healthcare Distribution Management Association**

**Testimony Before the Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives**

**Statement of
Elizabeth A. Gallenagh
Vice President, Government Affairs and General Counsel
Healthcare Distribution Management Association
April 25, 2013**

Good morning Chairman Pitts, Ranking Member Pallone and Members of the Energy and Commerce Subcommittee on Health. I am Elizabeth Gallenagh, Vice President, Government Affairs and General Counsel for the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to inform the Subcommittee regarding the critically important issue of prescription drug pedigree and pharmaceutical supply chain safety. I also would like to thank Chairman Upton, Congressman Latta and Congressman Matheson for their leadership in this area.

HDMA represents the nation's primary pharmaceutical distributors that deliver more than nine million prescription drugs and other healthcare products every day to 200,000 pharmacy and provider settings across the country.

Our 33 member companies purchase products from manufacturers and are responsible for storing, managing and delivering nearly 90 percent of all prescription medicines sold in the U.S. This critical public health function is performed with tremendous efficiency, resulting in nearly \$42 billion in annual savings to the nation's healthcare system.

The pharmaceutical distribution industry's primary mission is to operate the safest, most secure and efficient supply chain in the world. As part of this mission, HDMA's members work

to eliminate counterfeit and diverted medicines by capitalizing on the technological innovation and constant improvements in efficiency that are the foundation of our industry.

Today, I am here to express HDMA's strong support for a national, uniform approach to pedigree and the traceability of medicines throughout the supply chain. We support the core elements of the Latta-Matheson proposal and look forward to working with you and your Senate colleagues to enact federal legislation.

HDMA supports enhanced national wholesaler licensing standards and a new federal ceiling for pedigree and traceability requirements to improve safety and uniformity across the country, while establishing the foundation for longer-term electronic solutions, such as unit-level serialization and product tracing.

In addition to fundamentally addressing counterfeit and diverted medicines, a national approach to pedigree and traceability may be a useful tool in discouraging gray market activities associated with drug products in short supply. More importantly, it will put the U.S. on par with countries around the world engaging in serialization and traceability efforts.

After many years of debate, it appears that Congress finally may be poised to enact federal pedigree legislation. This is, in large part, due to a broad consensus among supply chain partners as well as growing support from Members of Congress and the leadership of Congressmen Latta and Matheson. While Congress, FDA and industry stakeholders have been working at this diligently for several years, it is critical that Congress act now due to the uncertainties faced by the industry, the need for uniformity across the supply chain and to ensure patient safety.

Because of the unique role HDMA members play in the supply chain between manufacturers and providers, they witness firsthand the complexities of dealing with the current 50-state patchwork of licensing and pedigree laws (see attached map of state pedigree legislation and regulations).

Basic guidelines for pedigree were set forth nearly 25 years ago with the enactment of the federal Prescription Drug Marketing Act (PDMA). Since that time, activity at the state level has varied with some enacting complex electronic pedigree laws and others never going further than the original 1988 guidelines. Based on our experience, the complexities of dealing with multiple approaches in the states will only get worse if we fail to solve this problem now, at the national level.

Since Florida's first foray into raising pedigree and licensure requirements in 2003, we have seen dramatic variations across the country in both legislative activity and regulatory interpretation. This variation has occurred despite HDMA's attempts to work in every state along with fellow stakeholders and interested legislators and regulators to achieve more uniformity. Today, for example, 29 states have acted beyond the federal PDMA standards. The states of Florida and California are viewed as leaders in this arena. However, they take completely different approaches, with Florida considered to be the most stringent in terms of today's requirements, and California's law thought to be the most complex, with track-and-trace and electronic pedigree implementation beginning in 2015.

This patchwork not only creates operational challenges, but also leaves openings for bad actors to shop around for more lenient state rules — openings that could mean the difference between a fake or diverted medicine being dispensed or administered to an innocent patient in

need of treatment. Because of this state-by-state variation, we believe that pedigree and traceability should be under the purview of Congress and the FDA.

HDMA has been a leader in this area, forming and participating in industry task forces and working groups that bring together manufacturers, distributors and pharmacies dedicated to identifying the operational and technical requirements for electronic pedigree, track-and-trace and traceability implementation. HDMA is also an active member of PDSA, the Pharmaceutical Distribution Security Alliance.

A comprehensive, practical approach would result in increased safety, continued efficiencies and minimal inconsistencies among competing state requirements — all of which will enable HDMA distributors and our supply chain partners to continue to deliver prescription drugs safely and efficiently every day.

HDMA commends Congressmen Latta and Matheson, along with the committee leadership, on continuing the dialogue and moving this effort forward with the release of the Latta-Matheson discussion draft. We believe that the framework of the draft is consistent with the basic foundation HDMA has supported through the years.

The bipartisan proposal includes the following core elements:

- National Uniformity

Adoption of national requirements for wholesaler licensing standards while preserving the states' ability to license and enforce, as well as uniform direct-purchase and standard pedigree (documentation of product transaction history) requirements. Taking this immediate first step will help to ensure the efficient flow of prescription drugs in

interstate commerce, raise the bar for states that have not gone beyond the current federal PDMA “floor” and enhance protections for the most secure prescription drug supply chain in the world — further ensuring patient safety and access to lifesaving medicines.

- Unit-level Serialization

Currently, there is no mechanism required to identify a unique bottle of medicine. This proposal will require manufacturers to apply a unique identifier to prescription drugs at the unit and case levels. This would be the first in a series of steps designed to help protect the supply chain against counterfeit, adulterated or other substandard products by facilitating improved ability to identify non-legitimate items. Prescription drugs would be identified at the unit and case level with a serial number (SNI), lot number and expiration date.

- Data Exchange and Systems Development

Once product is serialized, it is believed that product traceability initially can be achieved at the lot level, with potential for traceability at more discrete levels as systems mature. As a result, exchange of transaction data will be possible and can be leveraged to provide additional efficiency and safety benefits within the supply chain. HDMA supports a migration toward traceability that includes deliberate, careful evaluation and assessment by FDA and stakeholders at each step.

There is no single element that will protect the supply chain from every threat but rather, a comprehensive solution should incorporate each of these elements.

We applaud the work that has been done to date and urge the Subcommittee to act on this important issue this year. Now is the time for Congress to act to bring cohesion and consistency to our national drug supply chain.

Thank you.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes Ms. Simmon for 5 minutes for an opening statement.

STATEMENT OF CHRISTINE M. SIMMON

Ms. SIMMON. Thank you. Good morning, Chairman Pitts, Ranking Member Pallone and members of the Subcommittee. Thank you for inviting me to testify here today on the important topic of securing our Nation's pharmaceutical supply chain. I am Christine Simmon, Senior Vice President of Policy at the Generic Pharmaceutical Association. We represent the finished-dose generic drug manufacturers and bulk pharmaceuticals and suppliers to the industry.

For the past year, the effort to develop a national solution to securing the supply chain received strong support from key members in both the House and Senate but unfortunately was not enacted into law. We applaud this Committee for taking up this issue today, and we recognize and appreciate the dedicated attention to this issue and leadership by Congressmen Latta and Matheson.

GPhA believes that every patient in America deserves a safe and secure prescription drug supply. For many years, GPhA has worked closely with multiple stakeholders across the supply chain to ensure just that. As the makers of 80 percent of scripts dispensed in the United States, our industry is deeply committed to preventing and detecting the distribution and sale of counterfeit and adulterated medicines. We strongly supported last Congress's historic Generic Drug User Fee Act, which recognizes that while providing earlier access to medicines is critical, FDA's central mission is ensuring drug safety. We applaud the efforts of this Committee in enacting the user fee program into law.

GPhA is a member of the Pharmaceutical Distribution Security Alliance along with many others in the supply chain and including others at this table. The group's primary goal is to ensure patients have uninterrupted access to safe, authentic FDA-approved medicine. So today I am going to share with you our support for a system build on three core principles: a uniform federal standard, technical requirements that support achievability, and a building block approach to ensuring orderly implementation and avoid unintended consequences.

It is vital to ensure that any supply chain security system put in place is practical, focused, and uniform across the country. California's drug pedigree model that will be effective in 2015 would require implementation of full electronic track-and-trace capabilities where the entire distribution history and location of every unit in the supply chain can be determined at any time. At present, the technology to support such a system is unproven and the costs associated would be billions. Any attempt to hastily implement such a system could lead to confusion in the supply chain, aggravate product shortages and dramatically increase costs for all prescriptions including generic medicines.

In contrast, GPhA believes that a building block enables the industry to attain interoperability in achievable steps all the while applying the knowledge and experience gained over time to refine the model. While the generic industry is still reviewing recently re-

leased drafts, many elements are consistent with our proposed approach.

Specifically, as outlined in Phase I of the Latta-Matheson Discussion Draft, generic manufacturers have committed to identifying individual saleable units of medicine with labels and maintaining and managing data in their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of the products. Verification that a specific unit was serialized by a manufacturer within a given production lot can provide information and security that is a major step forward from current practices. The system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the unique identifier of a product at the unit level.

The stepped approach in the House draft would provide immediate measures to increase supply chain security. The system established under the proposals will improve the efficiency and effectiveness of drug recalls and returns. In planning for the future, it would provide critical building blocks that can be expanded as public health threat standards and technologies evolve.

Because American consumers today expect the convenience and simplicity inherent in the digital transfer of information, GPhA strongly supports the e-labeling requirement in the discussion draft to provide more standardized electronic prescription drug information that would increase patient safety and provide significant quality improvements and cost reductions through a more accurate, cost-effective, and sustainable alternative to paper inserts.

In conclusion, Mr. Chairman, GPhA and the industry share the concerns of the committee with regard to maintaining the security of our country's drug supply. The development of a uniform National system is needed to give regulatory authorities another tool for enforcement, make it more difficult for criminals to breach the supply chain, and enhance the ability of the supply chain to respond quickly when a breach has occurred. We believe the model proposed by the House includes many elements to achieve these goals. We look forward to working together with Congress to develop a consensus measure on this important issue that can be enacted into law.

Thank you, and I would be happy to answer any questions you may have.

[The prepared statement of Ms. Simmon follows:]



TESTIMONY OF CHRISTINE SIMMON

SENIOR VICE PRESIDENT, POLICY & STRATEGIC ALLIANCES

GENERIC PHARMACEUTICAL ASSOCIATION

**“SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY
CHAIN”**

BEFORE THE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

APRIL 25, 2013

Good morning Chairman Pitts, Ranking Member Pallone and Members of the House Energy and Commerce Subcommittee on Health. Thank you for inviting me to testify before the subcommittee on the important topic of securing our nation's pharmaceutical supply chain.

I am Christine Simmon, Senior Vice President, Policy & Strategic Alliances at the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, bulk pharmaceuticals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the United States, but account for only 27 percent of the total spending for prescription medicines. According to an analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts has saved U.S. consumers, patients and the health care system more than \$1 trillion over the past decade and \$192.8 billion in 2011 alone — which equates to \$1 billion in savings every other day. The quality and affordability of generic medicines is vital to public health and the sustainability of the health care system.

Introduction

For many years, GPhA has worked closely with multiple stakeholders across the supply chain to ensure that American consumers will continue to benefit from the safest and most secure prescription drug supply in the world. Both industry and the FDA are

exceptionally vigilant against the distribution and sale of counterfeit and adulterated medicines.

Any presence of counterfeit and adulterated pharmaceuticals in our supply chain threatens both the health of patients and the integrity of our industry. As the makers of 80 percent of the prescriptions dispensed in the United States, the generic pharmaceutical industry is deeply committed to ensuring the security of our country's drug supply. GPhA believes that the problem of counterfeit medicines raises a significant public health concern that must be addressed systemically on a range of levels — from local to global, and throughout the drug supply chain.

Our commitment to this issue is further evidenced by our industry's strong support of last Congress' historic Generic Drug User Fee Act, which recognizes that while providing earlier access to effective medicines is critical — and the key aim of all other existing user fee programs — FDA's central mission is ensuring drug safety. We also applaud the efforts of this Committee in enacting the user fee program into law. The program holds all players, foreign or domestic, contributing to the U.S. generic drug system to the same Good Manufacturing Practices (GMP), and inspection standards, while expediting access to more affordable, high quality generic drugs; the generic drug user fee program also enhances FDA's ability to identify, track and require the registration of all contributors involved in each generic drug product sold in the U.S.

We also are members of the Pharmaceutical Distribution Security Alliance, or PDSA:

a multi-stakeholder and interdisciplinary initiative whose membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers and pharmacies.

The PDSA's mission is to develop, and help enact, a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. The coalition's primary goal is to ensure patients have uninterrupted access to safe, authentic, FDA-approved medicine.

It is worth noting that low-cost generic drugs are rarely, if ever, targeted by counterfeiters. And in general, as the FDA acknowledges, "counterfeiting is quite rare within the U.S. drug distribution system." Nevertheless, the generic industry has been a leader in supporting numerous anti-counterfeiting efforts and developing methods to further protect the integrity of the pharmaceutical supply chain. The generic industry is committed to ensuring the safety of the millions of consumers nationwide who use safe, affordable generic medications. As such, we support a system built on the core principles of: a uniform, federal standard; technical requirements that support achievability; and a building-block approach to ensure an orderly implementation and avoid unintended consequences.

Last year, the effort to enact a national solution received strong support from key members in both the House and Senate but unfortunately was not enacted into law. We

applaud this Committee for picking up where the previous effort left off, and we recognize and appreciate the dedicated attention to this issue given by Congressman Matheson and Congressman Latta.

Uniform Federal Standard

As these efforts move forward, however, it is vital to ensure that any system is practical, focused, and uniform across the country. A uniform system founded on reliable technology and business practices would preclude the unintended consequence of erecting cost barriers to the distribution of safe and effective medicines.

For example, some anti-counterfeiting efforts, such as the drug pedigree model currently set to take effect in 2015 under California law, would require implementation of full electronic "track-and-trace" capabilities, where the entire distribution history, and the location, of every unit in the supply chain can be determined at any time. At present, the technology to support such a system is unreliable and underdeveloped, and the costs associated with such a model would be billions. Considering the myriad of manufacturers, packaging operations and potential exceptions, this is not a realistic expectation. An attempt to implement such a system would lead to confusion in the supply chain, aggravate product shortages and dramatically increase costs for all prescriptions, including generic medicines. The California law does include language providing for preemption of its requirements in the event that federal legislation is enacted, which we support.

Achievability

As the Committee begins its consideration of legislation to address this important issue, it is critical to understand how previous efforts at regulating the pharmaceutical supply chain — at both the state and federal level — have led us to where we stand today.

In 1988, Congress passed the Prescription Drug Marketing Act, or PDMA, requiring drugs to be tracked when they passed outside of the normal chain of distribution, which begins at the manufacturer, goes to authorized distributors and finally to the pharmacy. Congress found this necessary because the majority of drugs that were counterfeit, stolen, expired or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute a manufacturer's product. Manufacturers and their authorized distributors were exempted from these requirements, because the introduction of counterfeit medicines would rarely, if ever, occur in this link of the supply chain. However, the law was stayed by the FDA, and finally enjoined in 2006 by a federal district court in New York, in large part because the creation of a national drug tracking system including all supply chain participants had not been mandated, making the requirements potentially too difficult or impossible to fulfill for many legitimate distributors.

Since that time, this Committee and the Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which directs the FDA to develop standards for the identification, validation, authentication and tracking of prescription drugs, as well as a standard numerical identifier to be applied to a prescription drug at

the point of manufacturing and repackaging. While most of these standards have yet to be established, the FDA envisions a full track-and-trace system similar to that in California. We believe that the technology and processes necessary to achieve full track-and-trace are not fully mature at this time.

Additional federal legislation also has been introduced in recent years that would urge the establishment of national standards for an electronic tracking system. These proposals pursue the worthy goal of a single, uniform national standard for supply chain security, as opposed to a patchwork of differing state-by-state laws. However, the measures proposed would ultimately require an extensive track-and-trace model for each individual saleable unit of medicine that is simply unachievable within the proposed timeframes. GPhA believes that adoption of the California model, or one with very similar features, would raise the cost of medicine by billions of dollars over time, would be prone to error, and would have, at best, similar results to a less-expensive, more efficient model.

Building-block Approach

GPhA recognized the shortcomings of the California-type approach early on and proposed its own alternative model in 2011 by publishing a white paper on an end-point authentication model. At that time, we began to work in PDSA with representatives from all sectors of the supply chain and helped create an industry consensus model that we believe makes large safety strides in incremental steps over time. We believe that a building-block approach enables the industry to achieve the necessary interoperability in

achievable steps, all the while applying the knowledge and experience gained over time to refine the model. While our member companies are still reviewing the recently-released House draft, many elements of that draft are consistent with our proposed approach.

Specifically, as outlined in Phase I of the Latta-Matheson discussion draft, generic manufacturers have committed to identifying individual saleable units of medicine with labels, and maintaining and managing data in their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of products. Verification that a specific unit was indeed identified by a manufacturer within a given production lot can provide information and security that is a major step forward from current practices. Unit-level identification provides greater granularity of a lot and improves the visibility of its distribution throughout the supply chain, and also provides unit-level data as an additional check. This system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the identifier of a product at the unit level.

And unlike a full track-and-trace system, which we do not believe is technologically feasible in the near term, the House language would provide immediate measures to increase supply chain security. The system established under the proposal will improve the efficiency and effectiveness of drug recalls and returns. In planning for the future, it would provide critical building blocks that can be expanded as public health threats, interoperability standards, and technologies evolve, and establish connectivity and

infrastructure throughout the supply chain that will enable a variety of other capabilities and efficiencies. We also strongly support the e-labeling requirement in the discussion draft to provide more standardized, electronic prescription drug information that would increase patient safety and provide significant quality improvements and cost reductions to patients, manufacturers, prescribers and providers of pharmaceuticals by developing a more accurate, cost-effective and sustainable alternative to existing paper inserts. The discussion draft would also create more stringent federal standards and state licensing for wholesale distributors, and streamline requirements for manufacturers who also operate as distributors.

In keeping with many years of existing law, GPhA agrees with the Latta-Matheson discussion draft that intravenous (IV) products must be exempted from these regulations and urges that this exemption be maintained.

In short, the House proposal will replace the patchwork of inconsistent state laws, while increasing patient safety and enhancing our ability to identify and prevent the introduction of suspect products. It is important to recognize the limitations of technology and the necessity of other means of vigilance to address the issues of counterfeiting and diversion of drugs. There is no technology or tracking system that will stop all thieves and counterfeiters from attempting to divert products, or profit illegally.

GPhA supports the development of pilot programs to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain as well as the inclusion in the discussion draft of report mandates for the Government Accountability Office and Food and Drug Administration to assess implementation and pilot programs, respectively.

Conclusion

In conclusion, Mr. Chairman, GPhA and the industry share the concerns of the Committee with regard to maintaining the security of our country's drug supply and preventing the entry of counterfeit, diverted, stolen or other substandard medicines. The development of a uniform, national system is needed to give regulatory authorities another tool for enforcement, make it more difficult for criminals to breach the supply chain and enhance the ability of the supply chain to respond quickly when a breach has occurred. We believe the model proposed by the House includes many elements to achieve these goals. We look forward to working together with the House and Senate to develop a consensus measure on this important issue that can be enacted into law. Thank you and I would happy to answer any questions you may have.

Mr. PITTS. The Chair thanks the gentlelady and now the Chair recognizes Mr. Rose for 5 minutes for an opening statement.

STATEMENT OF MICHAEL ROSE

Mr. ROSE. Thank you for your introduction, Mr. Chairman, and thank you, Mr. Pallone. I work for and am representing Johnson and Johnson Health Care Systems Inc. Johnson and Johnson Health Care Systems Inc. is the principle supply chain commercial entity within the Johnson and Johnson family of companies in the United States.

Securing our Nation's supply chain is an important concern for our company. We believe it is vital for the patients who use our products receive our genuine products. We have already taken steps to secure our supply chain and protect our products. As a member of PhRMA and BIO and a participant in PDSA, I will share with you our perspectives on serialization and track-and-trace, our serialization experience and views on the draft legislation.

Serialization regulations have become increasingly common across many countries including the European Union, Turkey, Argentina, China, India, and Brazil. In the United States, the California law requires manufacturers to serialize and pedigree all pharmaceutical products sold in the State of California 50 percent of our products by January 1, 2015, and the remaining 50 percent by January 1, 2016. Additionally, more than 50 percent of the States have pedigree laws with varying approaches, that is, some require electronic pedigrees, others use paper. Some start the pedigree at the primary distributors, others will start it with the secondary wholesaler, et cetera. This patchwork quilt of regulations leaves us with a complicated, inefficient regulatory landscape creating unforeseen gaps where bad actors can introduce illicit drugs into the legitimate supply chain, thereby placing our citizens at risk of counterfeit medicines.

While the risk of encountering counterfeit medicines may be small within the legitimate domestic supply chain, when a patient receives a counterfeit medicine, the effects can be extremely dangerous, have long-lasting impact and can even be life-threatening. Our company believes that Federal Serialization and Track-and-Trace legislation is necessary to properly secure our pharmaceutical supply chain by eliminating varying and conflicting State regulations. Federal legislation should help close the gaps where illicit drugs enter the U.S. supply chain as well as provide additional mechanisms to help authenticate the legitimacy of medicines distributed and dispensed within the United States to help protect the patients who use our medicines.

Next I would like to share our company's domestic serialization experience. We are preparing our packaging sites, distribution centers, business and information technology systems to serialize and track and trace our products so that we can comply with the California e-pedigree law. Here is an example of the first product that we have serialized for the U.S. market. This product is Prezista 600-milligram tablets. For your reference, I have attached a label of serialized Prezista 600 milligrams to my testimony.

Let me draw your attention to the product license plate on the side of the label. This space is similar to the prescription drug product identifier prescribed in the House bill. We provide both machine and human readable forms for easy and accurate identification. Similarly, we apply a standard serialized barcode to every homogenous case to facilitate handling during distribution. This identification space complies with both the FDA's serial number identifier guidance and the widely adopted international standards developed by GS-1.

Additionally, we are establishing processes to exchange serialized data with the distributors who distribute our products and with the pharmacies that dispense our medicines to patients who need them. We are required to provide this information to the distributors and pharmacies so that they can use it to help verify both the authenticity of the package as well as the transactions related to the product.

Bottom line: While it is complicated work and a lot still remains, we are doing our part to comply with the California law. However, if any States were to adopt slightly different regulations, the inconsistencies could compromise the integrity of the supply chain, hence supporting the need for Federal action now to secure our National security chain.

Lastly, I would like to comment on the proposed legislation. In 2011, our company along with several other PhRMA and BIO members, and other supply chain participants helped form PDSA. PDSA's mission is to help enact a Federal policy proposal for one unified national system enhancing the security of the domestic supply chain for patients and to define a migratory implementation pathway.

Johnson and Johnson Health Care Systems supports Representatives Latta and Matheson for tackling this important issue and making progress on a legislative solution. This legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation. It is vitally important that both government and the private sector work together to protect our national drug supply in a manner that makes sense. We believe this legislation will help us secure the domestic pharmaceutical supply chain by providing additional protection to our citizens, patients who depend on the integrity of our medicines to treat their diseases and life-threatening conditions from counterfeit medicines. Johnson and Johnson Health Care Systems' commitment to patient safety is unwavering. We look forward to Congress's enactment of this legislation and we are committed to work with Congress, the FDA and our supply chain stakeholders to implement it successfully. Again, thank you for the opportunity to provide this testimony to the Committee.

Before concluding my remarks, I would like to recognize Steve Drucker, an industry colleague from Merck, who passed away last week. We will miss Steve's immense contributions, commitment to patient safety and especially his humorous insights. Our thoughts and prayers go out to Steve's family, especially his wife Ann and the entire Merck team.

[The prepared statement of Mr. Rose follows:]



425 Hoes Lane
Piscataway, NJ 08855

April 25, 2013

Thank you for your introduction, Mr. Chairman. I work for, and am representing, Johnson & Johnson Health Care Systems Inc. Johnson & Johnson Health Care Systems Inc. is the principal supply chain commercial entity within the Johnson & Johnson Family of Companies in the U.S. Thank you for the opportunity to speak here today. Securing Our Nation Supply Chain is an important concern for our company.

We believe it is vital that the patients who use our products receive our genuine products. We have already taken steps to secure our supply chain and protect our products. As a member of PhRMA (Pharmaceutical Research and Manufacturers of America) and BIO (Biotechnology Industry Organization), and a participant in PDSA - the Pharmaceutical Distribution Security Alliance, I will share with you our perspectives on serialization and track & trace, our serialization experience, and views on the proposed legislation.

Serialization regulations have become increasingly common across many countries, including the European Union, Turkey, Argentina, China, India, and Brazil.

In the U.S., the California law requires manufacturers to serialize and pedigree all pharmaceutical products sold in the State of California – 50 percent of our products by January 1, 2015 and the remaining 50 percent by January 1, 2016. Additionally, more than 50 percent of the states have pedigree laws with varying approaches – that is, some require electronic pedigrees, others use paper, some start the pedigree with the primary distributor, others start it with the secondary wholesaler, etc.

This patchwork quilt of regulations leaves us with a complicated, inefficient regulatory landscape, creating unforeseen gaps where bad actors can introduce illicit drugs into the legitimate supply chain, thereby, placing our citizens at risk of counterfeit medicines. While the risk of encountering counterfeit medicines may be small within the legitimate domestic supply chain, when a patient receives a counterfeit medicine, the effects can be extremely dangerous, have long lasting impact, and can be even life threatening.

Our company believes that Federal serialization and track & trace legislation is necessary to properly secure our pharmaceutical supply chain by eliminating varying and conflicting state

regulations. Federal legislation should help close the gaps where illicit drugs enter the U.S. supply chain, as well as provide additional mechanisms to help authenticate the legitimacy of medicines distributed and dispensed within the US to help protect the patients who use our medicines.

Next, I'd like to share our company's domestic serialization experience.

We are preparing our packaging sites, distribution centers, business and information technology systems to serialize and track & trace our products so that we can comply with the California e-Pedigree law. Here is an example of the first product that we have serialized for the U.S. market. This product is PREZISTA® (darunavir) 600mg tablets.

For your reference, I have attached a label of serialized PREZISTA® 600mg to my testimony.

Let me draw your attention to the product license plate on the side of the label. This space is similar to the Prescription Drug Product Identifier prescribed in the House bill. We provide both machine and human readable forms for easy, accurate identification. Similarly, we apply a standard, serialized bar code to every homogeneous case to facilitate handling during distribution. This identification space complies with both the FDA's Serial Number Identifier guidance, and the widely adopted international standards developed by GS1.

Additionally, we are establishing processes to exchange serialized data with the distributors who distribute our products, and with the pharmacies that dispense our medicines to patients who need them. We are required to provide this information to the distributors and pharmacies so that they can use it to help verify both the authenticity of the package as well as the transactions related to the product.

Bottom line, while it is complicated work and a lot still remains, we are doing our part to comply with the California law. However, if any other states were to adopt slightly different regulations, the inconsistencies could compromise the integrity of the supply chain, hence, supporting the need for Federal action now to secure our national supply chain.

Lastly, I would like to comment on the proposed legislation.

In 2011, our company, along with several other PhRMA and BIO members, and other supply chain participants helped form PDSA. PDSA's mission is to help enact a federal policy proposal for one unified national system enhancing the security of the domestic pharmaceutical distribution system for patients, and to define a migratory implementation pathway.

Johnson & Johnson Health Care Systems supports Representatives Latta and Matheson for tackling this important issue and making progress on a legislative solution. This legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation.

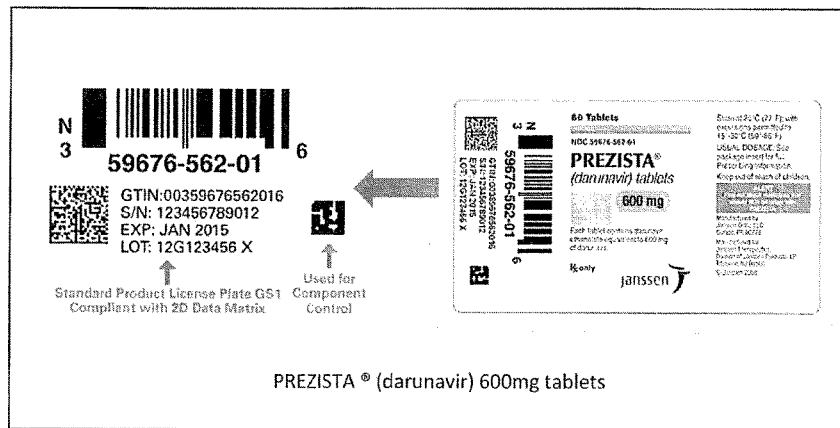
It is vitally important that both government and the private sector work together to protect our nation's drug supply in a manner that makes sense. We believe this legislation will help us secure the domestic pharmaceutical supply chain by providing additional protection to our citizens, patients who depend on the integrity of our medicines to treat their diseases and life-threatening conditions, from counterfeit medicines.

Johnson & Johnson Health Care Systems commitment to patient safety is unwavering. We look forward to Congress' enactment of this legislation, and we are committed to working with Congress, the FDA and our supply chain stakeholders to implement it successfully.

Again, thank you for the opportunity to provide this testimony to the Committee.

Before concluding my remarks, I'd like to recognize Steve Drucker, an industry colleague from Merck, who passed away last week. We will miss Steve's immense contributions; unwavering commitment to patient safety; and especially his humorous insights. Our thoughts and prayers go out to Steve's family, especially his wife, Anne; and to the entire Merck team.

Exhibit 1 - Serialized Label for PREZISTA® 600mg



Mr. PITTS. The Chair thanks the gentleman. Dr. Davis, you are recognized for 5 minutes for an opening statement.

STATEMENT OF TIM DAVIS

Mr. DAVIS. Chairman Pitts, Ranking Member Pallone and members of the Committee, thank you for conducting this hearing and for providing me the opportunity to share my perspective as an independent pharmacist and small business owner on the issue of securing the pharmaceutical supply chain. My name is Tim Davis of Beaver County, Pennsylvania, and I am the owner of Beaver Health Mart Pharmacy and have been a practicing pharmacist for over a dozen years. I am here today representing the National Community Pharmacists Association, which represents the pharmacist owners and employees of more than 23,000 independent community pharmacies in America. Our pharmacies provide over 40 percent of all community-based prescriptions.

It is my belief that the United States pharmaceutical supply chain is largely safe and secure. Most pharmacists today have a heightened awareness of counterfeit or diverted drugs and therefore recognize the critical importance of purchasing medications only from trusted trading partners. In addition, pharmacists, as part of our training and daily practice, carefully examine both drug packaging and the drug itself to be sure there are no suspicious anomalies.

It has been my observation, though, that certain types of prescription medications tend to be the target of counterfeiters. Relatively expensive drugs that can be easily produced and readily sold entice these bad actors. Some drugs that I have personally seen are lifestyle drugs, such as Viagra, and very costly injectable medications such as Procrit or more recently Avastin.

In response to concerns about the safety of prescription medications in the United States, over half of the States have passed drug pedigree laws that require drug products that move outside of normal distribution to be accompanied by a record of prior transactions. However, the differences in each State's laws has created a patchwork of activities across the United States. As a result, there have been past discussions about the practicality of a system that would track prescription drugs at the individual unit level. Pharmacists have had significant concerns about any system that would require each individual unit of medication to be electronically scanned upon arrival in a pharmacy due to the capital, time and labor costs associated with such a system. Presently, the technologies required to implement such a system are not fully developed, designed or scaled to be feasible or affordable for use in individual community pharmacies.

Of great concern is the California e-pedigree law that will begin to be implemented in 2015 that will require the electronic tracking and tracing of all drug packages in real time. This well-intentioned system will require each individual participant in the supply chain to scan each individual item to capture the transaction information. With each successive distribution, the e-pedigree must be updated with the newest transaction data as it makes its way to our pharmacies. In short, our pharmacies will have the unenviable task of maintaining all drug pedigree data for all distributions and must

be able to access it on demand. The cost of compliance with this law will be extremely high when factoring in both initial implementation and ongoing expenses necessary to maintain and access the data. Imposing these challenges, particularly on community pharmacies, is not logical at a time when the Nation is focused on trying to reduce health care costs.

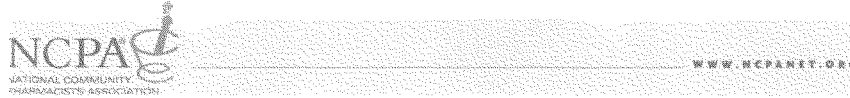
All of these factors bring us to a place in which we need a uniform federal framework to provide further assurances of supply chain security and that could be used to assist federal regulators in instances of drug recalls or inquiries. We need a reasonable, commonsense federal approach that will strike the appropriate balance between enhanced patient safety and minimizing unreasonable burdens on supply chain stakeholders, particularly small business pharmacies like myself.

NCPA is a member of the Pharmaceutical Distribution Security Alliance, a working group comprised of representatives of all sectors of the pharmaceutical supply chain, which has been collaborating over the past year and a half to address supply chain security issues. This group has reached a consensus around a number of topics. One is that of establishing National requirements for wholesaler licensure standards. Raising the standards for wholesaler licensure in a uniform fashion would provide the community pharmacist with an additional layer of confidence in the integrity of the medications purchased. The second concept is that of attaching a unique identifier to prescription drugs at the unit and case levels. Products would be identified with a two-dimensional matrix barcode including the serial number, lot number and expiration date. The PDSA coalition has also built consensus around being able to use the serialized identifier information to track products at the lot level. NCPA is pleased to note the inclusion of national wholesaler licensure standards, product serialization and lot-level tracking in both the recently released House discussion draft and the Senate draft. NCPA believes that the proposed lot-level system is one that could be built upon at some point in the future.

Community pharmacists take very seriously our role in ensuring the safety of medications that we personally dispense to our patients and we remain committed to working with our colleagues in the supply chain as well as with State and Federal authorities to make any needed improvements. Moving forward, it is essential that all stakeholders make a concerted effort to keep the lines of communication open so consumers can continue to trust the integrity of the medications that we all so depend on.

Thank you.

[The prepared statement of Mr. Davis follows:]



United States House Energy and Commerce Committee

Subcommittee on Health

Hearing on "Securing Our Nation's Prescription Drug Supply Chain"

**Testimony of Timothy Davis, Independent Pharmacist and Member of the
National Community Pharmacists Association**

April 25, 2013

Chairman Pitts, Ranking Member Pallone and Members of the Committee:

Thank you for conducting this hearing and for providing me the opportunity to share my views and perspective as an independent pharmacist and small business owner on the issue of securing the pharmaceutical supply chain. My name is Tim Davis of Beaver, Pennsylvania. I am the owner of Beaver Health Mart Pharmacy and have been a practicing pharmacist for 12 years. I am here today representing the National Community Pharmacists Association (NCPA) which represents the pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. These pharmacies provide about 40 percent of all community-based prescriptions.

It is my belief that the United States pharmaceutical supply chain is largely safe and secure. Most practicing pharmacists today have a heightened awareness of the possibility of counterfeit or diverted drugs and therefore recognize the critical importance of purchasing medications only from trusted trading partners or wholesalers.

In addition, pharmacists, as an integral part of their training and day to day practice, are taught to carefully examine and make note of both the drug packaging and the appearance of the drug itself to be sure there are no suspicious anomalies.

It has been my observation that certain types of prescription medications tend to be the target of counterfeiters or “bad actors” in the supply chain. Relatively expensive drugs that can be easily produced and readily sold enable counterfeiters to create an attractive profit margin. Some drugs that I have seen that are particularly susceptible are lifestyle drugs, such as Viagra, as well as very costly injectable medications such as Procrit or more recently Avastin, that are not always carried in community pharmacies, but rather are dispensed through consolidated specialty pharmacies, health systems, or directly by physicians. In my career, I have seen one example of counterfeiting at a local level. We received manufacturer information that a particular drug, Procrit, had entered the drug supply chain in counterfeit form and we were instructed how to recognize the genuine product against the fake. Upon receipt of a daily shipment from our local wholesale distributor, we checked and found that an item that we received was indeed one of the counterfeit products. We immediately contacted and discussed the situation with our wholesaler. Our particular solution was actually to stop doing business with that wholesaler due to the lack of a believable and reliable response.

In response to concerns about the safety of prescription medications in the United States, over half of the states have passed “drug pedigree laws” that require drug products that move outside of “normal distribution” to be accompanied by a “pedigree” or record of prior transactions. However, this approach and the differences in each state’s laws has created a “patchwork” of varying pedigree laws across the United States. Federal policy makers and supply chain participants alike have been discussing what a possible federal system to provide further assurances of supply chain security would look like for a number of years but due to the widely varying business models, financial resources and technological capabilities of those involved in the pharmaceutical supply chain, the process has not yielded a coherent, comprehensive national proposal yet on the federal level.

In the past, there have been numerous discussions about the practicality of a system that would track prescription drugs at the individual unit level. Pharmacists have had significant concerns about any system that would require each individual unit of medication to be electronically “scanned” upon arrival in a pharmacy due to the capital outlays that would be required and the time and labor costs associated with such a system. At the present time, the technologies that would be required to implement such a system are not fully developed and have not been designed or scaled to be feasible or affordable for use in individual community pharmacies.

Of great concern is the California “e-pedigree” law that will begin to be implemented for manufacturers in 2015 that will require the electronic tracking and tracing of all drug product packages, in real-time, in the drug distribution supply chain at the individual unit level through “electronic pedigrees” in an interoperable system. This well-intentioned system will require each individual participant in the supply chain to scan each individual item that will capture the transaction information. With each successive distribution, the e-pedigree must be updated with the new transaction data so that the e-pedigree continually grows as it makes its way to the pharmacy. In short, pharmacies will have the unenviable task of maintaining all drug pedigree data for all distributions above them and must be able to access it at any time. With the billions of drug product packages distributed, there will be billions of e-pedigrees and e-pedigree data that must be maintained and accessible—a massive amount of data. In addition, pharmacies must then pass back this information for each drug return.

The cost of compliance with this law will be extremely high especially for small community pharmacies—when factoring in both initial implementation and ongoing expenses necessary to maintain and access the data. Imposing these challenges particularly on small business supply chain participants like community pharmacies is not logical at a time when the nation is focused on trying to reduce the costs of healthcare.

All of these factors bring us to a place in which we need a uniform, federal framework to provide further assurances of supply chain security and that could be used to assist the FDA and other federal regulators in instances of recalls and other investigations. We need a reasonable, commonsense federal approach that will strike the appropriate balance between enhanced patient safety and minimizing unreasonable burdens on supply chain stakeholders, particularly small business pharmacies like myself.

NCPA is a member of the Pharmaceutical Distribution Security Alliance (PDSA), a working group comprised of representatives of all sectors of the pharmaceutical supply chain, which has been collaborating over the past year and a half to address supply chain security issues. The group has reached consensus around a number of different concepts. One of these concepts is that of establishing national requirements for wholesaler licensure standards. At the current time, there are some states in which the requirements necessary to obtain licensure as a drug wholesaler are less rigorous than others.

Raising the standards for wholesaler licensure in a uniform fashion would provide the community pharmacist at any location in the United States with an additional layer of confidence in the integrity of the medications purchased from such companies. The second concept is that of attaching a unique identifier to prescription drugs at the unit and case levels. Products would be identified at the unit and case level with a two dimensional matrix bar code including the serial number (SNI), lot number and expiration date for the product in machine and human readable form.

Once a product is serialized, this would essentially pave the way for all supply chain partners to eventually be able to use this data in increased ways and to be able to collaborate with one another to more easily locate particular products that may have been compromised in some way. The PDSA coalition has built consensus around being able to use the unique identifier information to track products at the lot-level. NCPA is pleased to note the inclusion of all of these consensus points in both the recently released House Discussion Draft and the Senate Discussion Draft. NCPA believes that the proposed lot-level system is one that could be built upon at some point in the future if it was determined that this was advisable and if there were significant inroads made on the associated technologies so that it would not be prohibitively expensive or burdensome for small business pharmacies.

I have a greater degree of confidence in the United States drug supply than I did just a few years ago—largely due to the heightened awareness of those in the supply chain to the possibility of counterfeit or diverted medications. That being said, community pharmacists take seriously our role in ensuring the safety of medications that we personally dispense to our patients and remain committed to working with our colleagues in the supply chain as well as with state and federal authorities to make any needed improvements. Moving forward, it is essential that all stakeholders make a concerted effort to keep the lines of communication open so that consumers can continue to trust the integrity of the medications that they depend on.

I appreciate the opportunity to address the Committee today and would be happy to address any questions that you may have.

Thank you.....

Mr. PITTS. The Chair thanks the gentleman. Mr. Coukell, you are recognized for 5 minutes for an opening statement.

STATEMENT OF ALLAN COUKELL

Mr. COUKELL. Chairman Pitts, Ranking Member Pallone and members of the Committee, thank you for the opportunity to testify. My name is Allan Coukell. I direct drug and medicine device work at The Pew Charitable Trusts, an independent research and public policy organization.

Pew supports the creation of a strong national system to protect American patients from the risks of counterfeit, stolen and diverted drugs. We do so based on our analysis of the risks to the supply chain and the feasibility of solutions. The principles that I will outline today are supported by other consumer, patient, public health and industry stakeholders, and I ask that a number of statements be included in the record with my written testimony.

There is general agreement on the need for a national system and how it would work. Manufacturers would put a unique serial number on each package of drugs. The drugs would be tracked as they pass from hand to hand through the complex distribution system and they could be checked to be sure they are authentic. This approach would bring the United States into line with other countries and individual States. Providing it creates a meaningful advance in safety, a single national system would be preferable to the current patchwork of State laws.

A recent example demonstrates how verifying a serial number on a drug package could have prevented a significant crime and risk to patients. Last year, the U.S. Attorney in New York charged 48 people in a large-scale diversion scheme to buy half a billion dollars worth of medicines from patients on the street, repackage them, sometimes with fake labels, and sell them back into distribution through licensed wholesalers who in turn sold the drug to pharmacies. This massive criminal recycling of government-subsidized drugs—similar schemes are well documented in other States—could be prevented if the drug package had a serial number and the serial number was retired after the drugs reached the pharmacy. This requires that pharmacies and wholesalers purchasing the drugs check that serial number. Without checking, the same serial, real or fake, could be sold again and again without detection.

Manufacturers are already making investments in drug serialization. To justify the expense and the preemption of strong State laws, it is essential that any Federal law achieve the following within a reasonable time frame: Participation of all members of the supply chain. We need traceability of drugs at the package level, not merely by lot, which can include thousands or tens of thousands of bottles, and routine checking of serial numbers. In a soon-to-be-released Pew Booz Allen Hamilton report, supply chain stakeholders overwhelmingly said that all sectors, manufacturers, distributors and pharmacies, need to participate in a national system without exception.

The technology is feasible, and package-level serialization and verification already exist or soon will in China, Brazil, Turkey, Italy and across the EU. A system that does not track drugs by the unit level would fail to catch unsafe drugs in many scenarios. Take

the example of a narcotic or any drug in shortage that is sold illegally or in the gray market. Without unit-level traceability, neither the purchaser nor an investigator would have any way to know who had sold that product or where it had come from.

Today, some companies are required to track a drug's transaction history through paper pedigree. An electronic system would be a welcome replacement, but Congress should certainly not replace pedigrees, which are used by regulators and law enforcement, with a structure that does less to capture the chain of custody than today's systems. Regular checking of drug serial numbers by supply chain partners is a powerful way to ensure that illegitimate products do not enter distribution. Take, for example, a truckload of insulin, 129,000 refrigerated vials, that was stolen from a highway rest stop a few years ago. After several months, some of that drug showed up on the shelves of chain drugstores in Texas, Georgia and Kentucky, having been handled by licensed wholesalers in at least two other States. Nobody knows how much of that product was resold but only 2 percent of it was recovered. We need a system that can flag suspect of illegitimate and flag it automatically.

Recognizing the danger, some companies have already taken steps. For example, the pharmaceutical company EMD Serono, after its human growth hormone was counterfeited, put in place a secure distribution program with unique serial numbers on each vial that are checked by the dispensing pharmacy. The core of that program shows how a national system can work.

Mr. Chairman, I thank you for this hearing and for your commitment to this issue. The discussion draft released by this committee a few days ago acknowledges the risks I have been describing. We urge you now to refine it to achieve the meaningful protections called for by patient, consumer and public health groups and the others I have mentioned. Indeed, we urge you to return to the bipartisan, bicameral, two-phased framework that you and your office and others on this committee have spent much of the past year developing, an approach that every organization represented on this panel has supported. It has been 25 years since PDMA. The California law will begin to be implemented in 2 years. The opportunity for a federal system now is great. We would like to work with this committee to improve this proposal to achieve a strong national system that achieves what it must: meaningful protections for patients.

Thank you, and I would welcome your questions.

[The prepared statement of Mr. Coukell follows:]

**Testimony before the Committee on Energy & Commerce, Subcommittee on Health
United States House of Representatives**

April 25, 2013

**Allan Coukell, director of drugs and medical devices
The Pew Charitable Trusts**

Chairman Pitts, Ranking Member Pallone, and members of the Committee, thank you for the opportunity to provide testimony. My name is Allan Coukell. I direct drug and medical device work at The Pew Charitable Trusts.

Pew is an independent, nonpartisan research and public policy organization dedicated to serving the public.

Based on our analysis of the risks to the drug distribution system and the feasibility of addressing those risks, Pew supports the creation of a strong national system to protect American patients from the risks of counterfeit, stolen and diverted drugs.

The principles I will outline today are supported by other stakeholders, and I ask that a number of statements from consumer, patient, public health and industry groups be included in the record with my written testimony.¹

There is general agreement on the need for a national system and how it would work. Manufacturers would put a unique serial number on each package of drug; the drugs would be tracked as they pass from hand to hand through the complex distribution system, and could be checked to ensure they are authentic.

This approach would bring us into line with standards in place in other countries and in individual U.S. states. Providing it creates a meaningful advance in safety, a single national system would be preferable to the current patchwork of 29 state drug pedigree laws.

Verification to prevent drug diversion

A recent example demonstrates how verifying a serial number on a drug package could have prevented a significant crime and risk to patients.

In July 2012, the U.S. Attorney for the Southern District of New York charged 48 individuals in a large-scale criminal diversion scheme to buy prescription drugs “on the street” from patients, re-package them and re-sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies.² The scheme included medicines for

HIV, schizophrenia, and asthma. In some cases, the criminals relabeled the drugs with new, fake labels.

This put patients at risk of counterfeit, outdated or mislabeled drugs. It also cost the Medicaid program in New York an estimated half-billion dollars. Similar schemes in other states are well documented, including one Tennessee in January of this year.³

This massive criminal recycling of government subsidized drugs could have been prevented by a serial number on a package. If the serial number was retired after the drugs reached the pharmacy, it would have been caught on its second trip around. Of course, that requires that the pharmacies and wholesalers purchasing the drug check that serial number. Without checking, the same serial number – real or fake – could be sold thousands of times over without detection.

Key elements of a national system

Pharmaceutical manufacturers are already making investments in drug serialization technology. To justify the expense – and the preemption of strong state laws – it is essential that any federal law achieve the following within a reasonable time frame:

- Participation of all members of the supply chain
- Traceability of drugs at the package level (not merely by lot, which includes thousands or tens of thousands of bottles), and
- Routine checking of drug serial numbers.

We have identified widespread support for measures to ensure that all members of the supply chain participate in a national system. In a soon-to-be-released study that Pew conducted with the consulting firm Booz Allen Hamilton, ten manufacturers, ten wholesalers, and eleven pharmacies were asked what features of a national unit-level serialization and traceability system were important to them.⁴ 80% of respondents said that all sectors in the supply chain needed to participate, without exception.

As I've mentioned, serialization beginning with the manufacturer and going through to verification by the dispenser is already in place or being implemented in other countries. China, Brazil, Turkey, Italy and the E.U. require (or will soon require) pharmacy authentication of serialized medicines in order to protect their citizens and prevent fraud.^{5,6,7,8}

Fortunately, a number of technological advancements, including cloud-based solutions, such as the one used in a 2012 track and trace pilot involving Abbott, McKesson, and the U.S. Department of Veterans Affairs, demonstrate how pharmacies may authenticate drugs and participate in a traceability system through use of a simple web portal.^{9,10}

Unit level serialization and traceability

Another key to improved security of drug distribution is knowing who handles the drugs as they move from manufacturer, through a succession of wholesalers, to the pharmacy or hospital and, ultimately, to the patient.

A system that tracks drugs by the lot number instead of at the unit level may provide incremental benefit over the status quo, but would fail to catch unsafe drugs in many scenarios. A lot can contain numerous cases of many thousands of individual bottles. Each may be sold separately, and lot-level tracing does not allow industry or regulators to know who bought and sold a given drug during distribution.

Take the example of a product like growth hormone or some other performance enhancing drug, or of a drug in shortage, that investigators discover is being sold in the grey or black market. Without unit-level traceability, there is no way to know which pharmacy, hospital or clinic may have possessed the products or had the inventory “leak”.

Today some companies are required to track a drug’s transaction history through paper “pedigrees”. An electronic system would be a welcome replacement to this paper-based paradigm; however, Congress should certainly not replace pedigrees, which are used by regulators and law enforcement, with a structure that does less to capture chain of custody than today’s system.

Routine checking of drug serial numbers

Regular checking of drug serial numbers by supply chain partners is a powerful way to ensure illegitimate products do not enter the distribution system and reach patients. In addition to preventing drug diversion, routine checking could also help the supply chain catch stolen and counterfeit drugs that criminals attempt to sell as legitimate products.

One example is the 2009 theft of a tractor-trailer containing 129,000 vials of insulin. This drug, which needs to be refrigerated, disappeared for a number of months before being sold back into distribution. Some of the stolen medicine was found at retail chain pharmacies in Texas, Georgia, and Kentucky, having passed through the hands of licensed wholesalers in at least two other states. But only 2 percent of that stolen inventory was ever recovered.^{11,12}

In another case, thieves stole \$75 million worth of pharmaceuticals from an Eli Lilly warehouse in Connecticut.¹³ Early last year those stolen drugs were discovered stored in South Florida.¹⁴ Had they been sold back into distribution no automated system would have flagged them for a pharmacy or wholesaler as stolen.

Counterfeits are another risk. Three times in a little more than a year, the FDA has announced the recovery of counterfeit Avastin® – a critical drug used to treat several types of cancer. In one of these cases, the supply chain included a licensed wholesaler in Tennessee. While we don’t

have full details about which members knew, or should have known, of the bogus product, the very existence of the fake drugs shows we can't be sanguine about the risks. Similarly, in 2001, counterfeit Serostim® — a human growth hormone used to treat AIDS-related wasting, was found in at least seven states and passed through multiple wholesalers.^{15,16,17} EMD Serono, the manufacturer of Serostim®, has since put in place a secured distribution program with a unique serial number assigned to each vial that must be verified by the dispensing pharmacy.¹⁸ Serono's program is an example of how drug distribution security can, and should, be improved.

Conclusion

I thank the Committee for holding this hearing and for its commitment to this issue. I also thank you for a discussion draft released this week. However this legislation, while it acknowledges the problem, does not offer a solution that will create meaningful protections for patients and does not address the comments that industry, patient, consumer, and public health groups made when Congress was contemplating this issue last year.

Congress first tried to address the kinds of risks I've been describing 25 years ago, through the Prescription Drug Marketing Act—a law that has never been fully implemented. Two years from now, California's comprehensive drug serialization law will begin to take effect. The opportunity today is great. We urge this committee to pursue a strong federal system that creates meaningful protections for patients.

Thank you again for the opportunity to testify, and I welcome your questions.

References

¹ These groups include the American Society of Radiation Oncology; the Cancer Support Community; Children's Cause for Cancer Advocacy; Fight Colorectal Cancer; International Myeloma Foundation; Kidney Cancer Association; the Leukemia and Lymphoma Society; National Coalition for Cancer Survivorship; National Lung Cancer Partnership; Ovarian Cancer National Alliance; Pancreatic Cancer Action Network; Prevent Cancer Foundation; Sarcoma Foundation of America; Susan G. Komen for the Cure Advocacy Alliance; Us TOO International Prostate Cancer Education and Support Network; the American Public Health Association; the Association of State and Territorial Health Officials; the National Association of County and City Health Officials; the Trust for America's Health ; Center for Medical Consumers ; Community Catalyst; Consumers Union; National Consumers League; National Research Center for Women & Families; National Women's Health Network; U.S. PIRG; WoodyMatters, along with , EMD Serono and Hewlett Packard.

² United States Attorney's Office, Southern District of New York. Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs. July 17, 2012. <http://www.justice.gov/usao/nys/pressreleases/july12/prescriptiondrugs.html> Accessed July 20, 2012

³ United States Attorney's Office for the Middle District of Tennessee. "Three Individuals Indicted For Prescription Drug Diversion Conspiracy". January 24, 2013. <http://www.justice.gov/usao/tnm/pressReleases/2013/1-24-13A.html>

⁴ Ten pharmaceutical manufacturers include five branded small molecule, one generic small molecule, three biopharmaceutical, and one contract packager. Ten pharmaceutical wholesalers include a range of business sizes, including one major national wholesaler. Eleven pharmaceutical dispensers include eight hospital pharmacies, one chain retail pharmacy, one independent pharmacy, and one mail-order pharmacy

⁵ Basta, Nicholas. "Serialization systems are going into operation around the world, but cross-industry collaboration awaits new legislation," Product Security Report, August 27, 2012
http://www.pharmaceuticalcommerce.com/index.php?pg=special_report&articleid=26610&keyword=2012%20product%20report-serialization-RxTEC.

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Mr. PITTS. The Chair thanks the gentleman. Dr. Catizone, you are recognized for 5 minutes for an opening statement.

STATEMENT OF CARMEN A. CATIZONE

Mr. CATIZONE. Chairman Pitts, Ranking Member Pallone and members of the subcommittee, I thank you for the opportunity to be here today. The National Association Boards of Pharmacy founded in 1904 and based in Illinois appreciates the chance to share with you comments and input from the States who are currently responsible for regulating this particular situation.

The issues before the committee are not new. In fact, the timeline in trying to secure our Nation's prescription drug supply extends far back than we care to admit. The activities that have ensued since the enactment of the PDMA some 25 years ago can best be characterized by two words: proposed and delayed. The language found throughout multiple Federal Register notices since the implementation of the PDMA read similarly over and over. The proposals presented by the FDA and supported by the States were continuously delayed and defeated by pressure from the industry.

As some of you may be aware, NABP is intimately involved in the oversight of wholesale distributors; as a result, our verified, accredited wholesale distributors program. To date, we have surveyed and accredited 552 wholesale distributors across the United States. We have observed firsthand and reported to the applicable State and federal authorities breaches in and compromises to the prescription drug supply chain. These breaches and compromises include the lack of a pedigree, the lack of complete information, the absence of any documentation, pedigrees or other transaction documents that indicate a product passed through multiple entities, some licensed and others not, multiple wholesaler companies located in a one-room business office in a strip mall claiming some form of common ownership, wholesalers receiving and storing products under conditions that render the medications adulterated or contaminated, and wholesalers and pharmacies establishing as their sole business model the purchase and sale of shortage drugs and inflating the price of these products by a thousandfold, an unconscionable action when it comes to drugs that are needed by patients suffering from life-threatening diseases such as cancer.

The States are both the frontline and last defense in the prescription supply chain. Together with NABP, they have forged an effective public-private partnership. That partnership was recognized by the Institute of Medicine in its report "Countering the Problem of Falsified and Substandard Drugs." The report notes that crime and corruption drive the business of falsified medicines and that medicines can change hands many times in myriad countries before they reach patients.

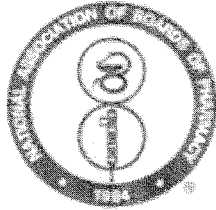
One of the primary recommendations of the IOM that is critical to the considerations before this committee and bears noting this afternoon was a recommendation they made in regard to NABP, and I quote: "The IOM committee calls for strengthening the drug distribution system in order to improve the quality of medicine and protect consumers. Top among its priorities is restricting the U.S. wholesale market to firms vetted by the National Association of Boards of Pharmacy. This action would tighten the American drug

distribution chain and build momentum for better controls on drug wholesalers in developing countries.”

NABP supports the implementation of a national system for the oversight and regulation of prescription drug supply chain provided such system is comprehensive and does not discard the protections already in place and ready for implementation by the States, particularly California. It should take into account the existing and successful public-private partnership established between the States and NABP endorsed by the Institute of Medicine and operating effectively at no cost to the American taxpayers. NABP calls for no further delays. The time has long passed for the continued delay in addressing and resolving the challenges confronting our Nation’s prescription drug chain. NABP requests that all participants in the supply chain be accountable. Exemptions should not be granted to pharmacies. NABP supports the tracking and traceability of products to the package level and made operational in 2015 and 2016 in order not to retreat on advances made by California and the timeline already committed to by a growing number of the industry. NABP supports pharmacies and wholesale distributors being required to append and pass pedigrees or other equivalent transaction documents within the next 2 to 4 years, and NABP supports providing the Food and Drug Administration with the full scope of authority and resources needed to implement and enforce a national system.

We thank you for the opportunity.

[The prepared statement of Mr. Catizone follows:]



Testimony Before the Committee on Energy &
Commerce, Subcommittee on Health
United States House of Representatives
April 25, 2013

Carmen Catizone, M.S., RPh, DPh, executive director
National Association of Boards of Pharmacy

Good morning Chairman Pitts, Ranking Member Pallone, and members of the Committee. The National Association of Boards of Pharmacy (NABP) appreciates the opportunity to appear before you today and provide information in regard to safeguarding the integrity of the nation's drug supply chain. I am Carmen Catizone, executive director of the Association.

NABP is the impartial professional organization that supports the state boards of pharmacy in protecting the public health. NABP aims to ensure the public's health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs.

Twenty Five Years of "Proposed" and "Delayed"

The issues before the Committee are not new. In fact the timeline for trying to secure our nation's prescription drug supply chain extends farther back than many would care to admit and farther back than should be permitted. Quoting from the FDA's web site: "The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law by the President April 12, 1988. The PDMA was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs."

The activities that ensued since that time can best be described using two words, "proposed" and "delayed." The language found throughout multiple Federal Register notices since the implementation of the PDMA 25 years ago read similarly over and over. One example reads "On February 23, 2004 (69 FR 8105), FDA published a delay of the effective date of certain requirements in a final rule published in the Federal Register of December 3, 1999 (64 FR 67720)." The proposals presented by the FDA and supported by the states were continuously delayed and defeated by pressure from the industry.

NABP supports the implementation of a national system for the oversight and regulation of the prescription drug supply chain provided such system is comprehensive and does not discard the effective protections already in place and readied for implementation by the states, particularly California. In addition, NABP supports a national system provided it allows the states to have input into the development and recognizes the authority of the states to implement necessary modifications to address significant instances that may arise and were not contemplated or included in any national proposal. The national system supported by NABP is absolutely essential to the protection of the public we serve and to ensuring that the medications patients across the United States are dispensed or administered are safe and not counterfeit, diverted, or injurious in any way.

As some of you may be aware, NABP is intimately involved in the oversight of wholesale distributors as a result of our Verified-Accredited Wholesale Distributors (VAWD) program. To date, NABP has surveyed and accredited approximately 552 wholesale distributors across the states. As a result of those surveys and the valuable information and expertise that NABP gained, we can report to you that some of the issues originally driving the enactment of the

PDMA in 1987 have been addressed and resolved. There are, however, still a number of critical concerns that threaten the distribution supply chain that must be addressed. It was our hope that many if not all of these issues would be the focus of legislation proposed and adopted by the House and Senate. Our analysis of the legislative proposal released just a few days ago indicates that it may not address these serious issues.

Besides some of the high profile abuses that have been reported in the media, NABP observed first hand and reported to the applicable state and federal authorities breaches in, and compromises to, the prescription drug supply chain. These breaches and compromises include, but are not limited to, the lack of complete or the absence entirely of pedigrees or other required transaction documents, pedigrees or other transaction documents that indicate a product passed through multiple entities some licensed and others not, multiple wholesaler companies located in a one-room strip mall business office claiming some form of common ownership, wholesalers receiving and storing products under conditions that render the medications adulterated or contaminated, and wholesalers and pharmacies, establishing as their sole operating model the purchase and sale of shortage drugs and inflating the prices of these products by a thousand-fold – an unconscionable action when it comes to drugs that are needed by patients suffering from life-threatening conditions such as cancer.

The States Serve as the Last Defense for Patients and Consumers

The states are both the front line and last line of defense in the prescription drug supply chain. Since the inception of the PDMA, the states have had to forge a system of oversight and regulation to protect the integrity of products in the supply chain absent a national system because for 25 years the industry has fought such state and federal efforts and delayed implementation of a proposed solution.

The Institute of Medicine's report, "Countering the Problem of Falsified and Substandard Drugs," notes that "crime and corruption drive the business of falsified medicines." The report further documents that "medicines can change hands many times in myriad countries before they reach patients." One of the primary recommendations of the IOM report is critical to the considerations before this Committee and bears noting this morning:

"The IOM committee calls for strengthening the drug distribution system in order to improve the quality of medicine and protect consumers. Top among its priorities is restricting the U.S. wholesale market to firms vetted by the National Association of Boards of Pharmacy. This action would tighten the American drug distribution chain and build momentum for better controls on drug wholesalers in developing countries."

Recommendations

1. Support the existing and successful public-private partnership system, VAWD that NABP established with the states and is endorsed by the Institute of Medicine. NABP asks the Committee to consider the priority recommendation of the IOM and support the effective public private partnership that currently exists between NABP and state and federal regulators, protecting the integrity of the drug supply chain at no cost to the American taxpayers.
2. No further delays. NABP believes that the time has long passed for any continued delay in addressing and resolving the challenges confronting our nation's prescription drug supply chain. The timeline for federal action in the proposed legislation extends the wait of consumers and patients for a protected supply chain to 35 years! California's requirements can be operational over the next three years and help to build the uniform and national standards that all stakeholders support. In comparison over the past 30 years the following notable advances occurred:
 - a. Internet, broadband, www (browser and html)
 - b. PC/laptop computers
 - c. Mobile phones
 - d. E-mail
 - e. DNA testing and sequencing/human genome mapping
 - f. Magnetic Resonance Imaging (MRI)
 - g. Microprocessors
 - h. Fiber optics
 - i. Office software (spreadsheets, word processors)
 - j. Non-invasive laser/robotic surgery (laparoscopy)
 - k. Open-source software and services (e.g., Linux, Wikipedia)
 - l. Light-emitting diodes
 - m. Liquid crystal display (LCD)
 - n. GPS systems
 - o. Online shopping/e-commerce/auctions (e.g., eBay)
 - p. Media file compression (jpeg, mpeg, mp3)
 - q. Microfinance
 - r. Photovoltaic solar energy
 - s. Large- scale wind turbines
 - t. Social networking via the Internet
 - u. Graphic user interface (GUI)
 - v. Digital photography/videography
 - w. RFID and applications (e.g., EZ Pass)
 - x. Genetically modified plants
 - y. Bio fuels
 - z. Bar codes and scanners
 - aa. ATMs
 - bb. Stents
 - cc. SRAM flash memory
 - dd. Anti-retroviral treatment for AIDS

3. All participants in the supply chain must be accountable. Exemptions should not be granted to pharmacies.
4. The tracking and traceability of products should be to the package level and operational in 2015 and 2016 in order not to retreat on the advances made by California and the timelines already committed to by a growing number of the industry.
5. Pharmacies and wholesale distributors must append and pass pedigrees or other equivalent transaction documents within the next two to four years.
6. Establish a process for the routine and regular verification of product serial numbers.
7. Provide the Food and Drug Administration (FDA) with the full scope of authority and resources needed to implement and enforce a national system.

Conclusion

NABP thanks the Committee for the opportunity to appear today and present information and concerns from the state boards of pharmacy. The Association and its member state agencies support a comprehensive national solution to the challenges facing the integrity of our prescription drug supply chain. However, that supply chain must place public safety first and not undo the significant advances made by the states and FDA to ensure that American citizens across the country receive safe and effective medications.

Thank you.

Mr. PITTS. The Chair thanks the gentleman. Mr. Berghahn, you are recognized for 5 minutes for an opening statement.

STATEMENT OF WALTER BERGHAHN

Mr. BERGHAHN. Thank you, and good afternoon. Chairman Pitts, Ranking Member Pallone, and members of the committee, I appreciate the opportunity to be here and share my perspective on this matter. My name is Walter Berghahn. I am the Executive Director of the Healthcare Compliance Packaging Council, a trade association dedicated to improving medication adherence and patient safety through broad adoption of innovative packaging. The HCPC represents packaging material and machinery suppliers as well as contract packagers. The members serve as pharmaceutical manufacturers and pharmacy both institutional and retail. The HCPC supports California's SB 1307 and the work of this committee, recognizing that we share the common goal of a secure supply chain.

The U.S. pharmaceutical supply chain is primarily safe. Drugs are produced, packaged and shipped according to FDA guidelines. They travel through a complex supply chain and arrive at the appropriate pharmacy, hospital and nursing home mostly without incident. That sounds wonderful, but that is not why we are here today. We are here because there are many groups intent on selling counterfeit or gray market drugs into the U.S. supply chain despite a tremendous effort over the last 10 years to secure the supply chain. Counterfeits are still appearing. The FDA has opened more investigations in recent years than ever before, more than 70 incidents in 2010 alone.

Some suggest that the cost to fix it is too high and the supply chain is safe enough. I am betting that those people have never had a family member ingest or inject a counterfeit medication and suffer the health consequences.

It has been suggested that serialization and barcoding technology is not mature or scalable enough for this task, and yet barcoding has been used since the 1970s. It is found in every store and pharmacy in America. Two-dimensional barcoding required for serialization is newer but well established. The Department of Defense issued a paper in 2005 outlining their use and implementation of 2D barcoding for tracking valuable items in both forward and reverse logistics. Every day, tens of millions of packages are tracked by FedEx and UPS utilizing serialized barcodes. Every day, 1½ million U.S. air travelers board planes using 2D serialized barcodes. I am not suggesting the process will be easy for pharmaceuticals but the technologies employed are proven and they are widespread.

California led the way on serialization with SB 1307 with initial targets in 2007 and subsequent delays allowing industry time to comply. I am sure you are familiar with the timeline. Pharmacy would be the last to comply in July of 2017, a full 4 years from today. The HCPC hopes that the federal legislation will support SB 1307 and not undermine its progress.

The packaging machinery industry is prepared to help meet these deadlines. Systems ranging from manual to fully automated exist which apply, verify and aggregate 2D barcoded containers to cases. Companies such as Systech, Optel, Seidenader, Omega and

numerous others are delivering these systems to branded and generic pharmaceutical manufacturers today. Dozens of systems have been installed in the United States in anticipation of California's deadlines. Hundreds more are being planned, ordered and constructed now. A larger number of systems have already been deployed globally to meet international requirements for serialization in countries like China, Brazil, Turkey, India and a large portion of the EU.

All this work does wonders for securing the normal supply chain but we would be remiss if we didn't consider the many documented problems occurring outside normal channels. So how do we detect those instances? In my opinion, the best way would be to provide prescriptions the way most of the world does: in the manufacturer's original container. This would accomplish two things. It thwarts the introduction of counterfeit products in pharmacy as well as dispensing of outdated and returned product, all unfortunately well documented. Secondly, it would allow the insurance industry to mandate the use of a serial ID for reimbursement, not simply the NDC number. This practice would greatly reduce prescription fraud. The government via CMS and the Veterans Administration is the largest payer in the United States and would see the largest benefit from this practice.

This is relevant because even the physicians cited in the recent Avastin counterfeit case in California need to submit for reimbursement. Today, all they need is a valid NDC number. In the future, requiring a serial number for reimbursement could block illegally purchased items from being distributed. California has documented cases where pharmacists have illegally purchased product over the Internet and dispensed them in pharmacies, submitting for reimbursement with a legitimate NDC. Could lot-level tracking have stopped this?

In conclusion, I would like to address one of the major differences between the proposed methodologies being considered. The debate is item-level tracking versus lot-level tracking. To be sure, lot-level tracking is less cumbersome on industry players but one must question its effectiveness. Lot-level tracking will provide tools for evaluating what happened, why a counterfeit drug got in the supply chain. Item-level track-and-trace will prevent it. The difference is staggering: prevention versus detection after the fact. I would hope that in considering which path to pursue, members will look at past instances of counterfeiting and ask a simple question: would lot-level tracking have prevented this product from entering the supply chain?

Thank you for the chance to contribute to this.

[The prepared statement of Mr. Berghahn follows:]

1 United States House Energy and Commerce Committee
2 Subcommittee on Health
3 Hearing on "Securing Our Nation's Prescription Drug Supply Chain"
4 Testimony of Walter Berghahn, Executive Director
5 The Healthcare Compliance Packaging Council
6

7 April 25, 2013
8

9 Chairman Pitts, Ranking Member Pallone and Members of the Committee:

10 Thank you for providing me the opportunity to share my views and perspective on this matter as
11 someone who has worked in and around the pharmaceutical supply chain for the last 17 years. My
12 name is Walter Berghahn and I am the Executive Director of the Healthcare Compliance Packaging
13 Council, a trade association dedicated to improving medication adherence and patient safety in the US
14 pharmaceutical supply chain through broad adoption of innovative packaging technology.
15 The HCPC represents packaging material and machinery manufacturers as well as contract packagers
16 who provide materials and packaging services to pharmaceutical manufacturers as well as downstream
17 customers in both institutional and retail pharmacy. This pending legislation and that already
18 established in California SB 1307 directly affects the membership and their customer base. That being
19 said, the membership of HCPC has been supportive of the legislation in California, recognizing that it's
20 goal is consistent with HCPC's, that of furthering pharmaceutical supply chain and patient safety.
21 For the most part, the US pharmaceutical supply chain is safe. Manufacturers, distributors and
22 pharmacies do their job day in and day out with patient safety in mind. Drugs are produced, packaged
23 and shipped according to FDA guidelines, they make their way through a complex supply chain and
24 arrive in the appropriate pharmacy, hospital or nursing home without incident.
25 Sounds wonderful but that's not why we're here today. We're here because there are individuals and
26 groups out there intent on selling counterfeit or gray market drugs into the US supply chain. There has
27 been a tremendous amount of effort expended in the last 10 years to tighten up and secure the supply
28 chain. Those efforts certainly have closed many of the cracks and yet counterfeits still
29 appear and the FDA has opened more investigations in the last few years than ever before, more than
30 70 incidents in 2010 alone. The companies and organizations testifying before you today are not the

31 problem. It is the exceptions, the unscrupulous players who knowingly subvert the system to introduce
32 counterfeit, gray market or substandard drugs into the supply chain for economic profit that must be
33 stopped. Some here would suggest that the cost is too high to stop the exceptions and that the supply
34 chain is safe enough.

35 I'm betting that those people have never had a family member or friend ingest or inject a counterfeit
36 medication and suffer health setbacks or worse as a result. It's easy to say it is too complicated and too
37 expensive when it hasn't hit you personally.

38 It's been suggested by many that serialization and bar coding technology is not robust, not mature
39 enough for this task and yet bar coding has been in use since the 70's. You cannot go into a store
40 including pharmacies in the US without encountering bar code readers. They are used for inventory
41 management throughout our retail marketplace. 2 dimensional bar coding which will be required for
42 serialization is not as old but is still well established. The Department of Defense issued a paper in 2005
43 outlining their use and implementation of 2D bar coding for tracking valuable items in both forward and
44 reverse logistics.

45 Everyday 10's of millions of packages are tracked by Fed Ex and UPS utilizing serialized barcodes to
46 provide item level visibility in transit. Everyday approximately 1.5 million air travelers in the US board
47 planes with 2D bar codes verifying who they are and that they are on the right flight. I'm not suggesting
48 by any means that this process will be easy for pharmaceuticals but the technologies employed are
49 proven and are actively used all around us on a daily basis.

50 On pharmaceuticals California led the way in the US requiring serialization on pharmaceutical containers
51 taking one step further than Florida's paper pedigree implementation in 2005 that did not track items.
52 California's SB 1307 has been more than generous with time for implementation with initial targets in
53 2007 and subsequent delays to allow industry time to comply. Currently the pharmaceutical
54 manufacturers would have to serialize 50% of their products by 2015. The rest of the supply chain sees
55 staggered implementation ending with pharmacy and pharmacy warehouses in July of 2017 more than 4
56 years from today. We would hope that any Federal Legislation would be supportive of California SB 1307
57 and build on their progress. The industry is actively preparing to meet the deadlines.

58 The supporting packaging machinery industry is well prepared. Various levels of systems ranging from
59 manual to fully automated exist which can apply, verify, and aggregate 2d bar coded containers in the
60 packaging process. Complete cases exit the packaging process in a pharmaceutical manufacturer or
61 contract packaging plant ready for entry into the supply chain. Companies such as Systech, Optel,
62 Seidenader, Omega, Antares, Laetus, PCE, Visiotec and numerous others are actively engaged in
63 delivering these systems to both branded and generic pharmaceutical manufacturers. Dozens of
64 systems have already been installed in the US in preparation for California and hundreds are in the
65 process of being planned, ordered and constructed. A much larger number have already been
66 deployed globally to meet international requirements for serialization in countries like China, Brazil,
67 Turkey, India and large portions of the EU.

68 All this work does wonders for securing the supply chain but we would be remiss if we didn't consider
 69 that these controls work well within the normal supply chain. Many of the documented problems occur
 70 outside normal channels. So how to protect or detect those instances ? In my opinion the best way
 71 would be to provide prescriptions the way most of the world does, in the manufacturers original
 72 container. This would accomplish two things.

73 1] it would thwart the introduction of counterfeit products in pharmacy which sadly has been
 74 documented, as well it would thwart dispensing of outdated and returned product, also well
 75 documented.

76 2] it would allow the insurance industry to require use of the serial ID for reimbursement, not simply the
 77 NDC. This practice would greatly reduce the opportunity for prescription insurance fraud. Since the
 78 government via CMS is the largest payer in the US reduction in prescription fraud would seem to be of
 79 interest.

80 Why would this be relevant ? Because even the physicians sited in the recent Avastin counterfeit case in
 81 California will submit for reimbursement on these medications. In today's system all they need is a valid
 82 NDC number which they can get easily. In the future if they are required to provide a serial number for
 83 a dispensed unit then they will not be able to submit illegally purchased items from the internet that did
 84 not travel through our secure supply chain. California has noted similar cases where pharmacists have
 85 illegally purchased product over the internet and dispensed them in pharmacy but submit for
 86 reimbursement with a legitimate NDC number. One has to question whether lot level tracking could
 87 stop such activity.

88 This same type of safety could even be extended to patients. It is not hard to imagine a system to allow
 89 patients to scan a 2d barcode using a smartphone to verify that the container they received is valid in
 90 fact companies like HP have already launched platforms with this capability for detecting counterfeits in
 91 other industries.

92 In conclusion I would like to address one major difference in the two proposed methodologies being
 93 considered. There has been a great deal of discussion about the benefits of item level tracking vs. Lot
 94 level tracking. To be sure, lot level tracking is less cumbersome on various industry players but one has
 95 to question its effectiveness. Lot level tracking will provide wonderful tools for evaluating what
 96 happened, why a counterfeit or diverted drug got into the supply chain. Item level track and trace is
 97 aimed at preventing counterfeit packages from entering the supply chain. The difference is staggering.
 98 Prevention vs detection after the fact. I would hope that in considering which path to pursue members
 99 would look at past instances of counterfeiting and ask the simple question: Would lot level have
 100 prevented this product from entering the supply chain.

101

102 Thank you for allowing me to provide input to this process.

Mr. PITTS. The Chair thanks the gentleman. That concludes the opening statements of our second panel. At this time I would like to request unanimous consent to place a statement from the National Association of Chain Drugstores into the record. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. You have a UC request?

Mr. PALLONE. Mr. Chairman, I would ask unanimous consent to enter into the record a letter from EMD Serono.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. All right. I will begin the questioning and recognize myself 5 minutes for that purpose.

I will start with Ms. Gallenagh. Talk a little bit about the California model. Would the California model work on a national level? Would you describe some of the consequences for patients and industry and others? We will go down the line and start with you, Ms. Gallenagh.

Ms. GALLENAGH. Sure. Based on what we know right now, a lot depends on the time frames that would be set forth on a national level. The California dates currently, in my opinion, would not be practical for a National model. Additionally, there is a piece of the California law that is providing to be particularly difficult in piloting, and that is the electronic pedigree portion of the law that also goes along with full track and trace of product electronically throughout the supply chain. And these are right now, based on what we are learning through experimenting with the processes and the technology very difficult for industry.

Mr. PITTS. Ms. Simmon?

Ms. SIMMON. Thank you. Yes, we would echo that. You know, some of the necessary technology, speaking from a manufacturer's point of view, just isn't really there yet. Aggregation of units to cases and pallets is not ready to be deployed with a high level of accuracy for the data that would be required, and some of the interoperability standards for the data are not yet solved. With the compliance dates only 2 years ago, you know, we feel that is moving too quickly to avoid some unintended consequences.

Mr. PITTS. Mr. Rose, would you comment on the consequences for industry and patients?

Mr. ROSE. Consequences on patients?

Mr. PITTS. Both industry and patients.

Mr. ROSE. OK. For industry, we brought a sample of our product where we have applied the 2D data matrix code with a serial number on it.

Mr. PITTS. And would you point out what you said in the testimony?

Mr. ROSE. Right here we have the 2D data matrix code, and then here we have human readable format where we have put the serial number in there as well as the product code and expiration date and lot, and you can read it human readable or via machinery. This took a lot of work to get going. The next phase we are working on right now is exchanging data with our trading partners. Those standards don't exist. We don't have guidance from California on those data standards, and we are missing those. That is very im-

portant to have for us to be fully compliant with the California law. So to achieve this date, we need those standards to be put in place but then also we have to put those systems in place to be able to exchange that data with our trading partners.

Mr. PITTS. Dr. Davis, would you care to comment?

Mr. DAVIS. I think that from a community pharmacist's perspective that it would be relatively difficult for us to comply nationwide because of a couple of reasons. One would be the ability to absorb and to maintain the costs associated with the system, and two, to access and be able to implement the technologies surrounding it. This is something external to all of our current processes in the field of pharmacy, and we don't want to necessarily lose the relationships and patient care experiences that we have currently in place in lieu of trying to comply by another national standard.

Mr. PITTS. Now, I posed several of these questions to FDA earlier today, and I would like to get the opinion of actors on the ground working to manufacture and distribute and dispense our Nation's drug supply, so if you will please respond. Will national uniformity increase the security of the supply chain and improve patient safety, Ms. Gallenagh?

Ms. GALLEENAGH. Yes.

Mr. PITTS. Ms. Simmon?

Ms. SIMMON. Yes, it would.

Mr. PITTS. Mr. Rose?

Mr. ROSE. Yes, it would.

Mr. PITTS. Dr. Davis?

Mr. DAVIS. Yes.

Mr. PITTS. What about—is it important to preserve the States' ability to license and enforce National standards?

Ms. GALLEENAGH. I would say yes, it is important so that they have a role to partner with FDA.

Mr. PITTS. Ms. Simmon?

Ms. SIMMON. Yes, we would agree as well.

Mr. ROSE. Yes, we would agree as well.

Mr. DAVIS. Yes.

Mr. PITTS. Will product serialization increase the security of the supply chain and improve patient safety?

Ms. GALLEENAGH. Yes, absolutely.

Ms. SIMMON. Yes, we definitely favor product serialization.

Mr. ROSE. We agree with product standardization.

Mr. DAVIS. And we agree with it as well in a phased-in approach so that we can build our systems and our capabilities without compromising patient care as it stands today.

Mr. PITTS. All right. Will data exchange and systems between actors in the supply chain increase the security of our drug supply and improve patient safety?

Ms. GALLEENAGH. Yes.

Ms. SIMMON. Yes, it would.

Mr. ROSE. Yes, it would.

Mr. DAVIS. Yes, it would.

Mr. PITTS. And finally, would a National track-and-trace standard increase the efficacy of product recalls?

Ms. GALLEENAGH. Yes, it would.

Ms. SIMMON. Yes, we believe it would.

Mr. ROSE. Yes.

Mr. DAVIS. Yes, it would, sir.

Mr. PITTS. Thank you. I have gone over time. The chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. I just wanted to follow up on Mr. Pitts' question going down the line, a yes or no because I have other questions. So OK, 2 years you are saying isn't workable but what about 10 years? Can the issues that we referenced here, track and trace, unit level, can they be worked out by then over 10 years? Yes or no, Ms. Gallenagh?

Ms. GALLEENAGH. I think that it is possible to get to a next step. I think that—

Mr. PALLONE. I am trying to get a yes or no, though, because otherwise I am going to run out of time. Or if you don't want to say yes or no, you can say maybe.

Ms. GALLEENAGH. I would say maybe.

Mr. PALLONE. All right. Ms. Simmon?

Ms. SIMMON. I would say maybe if it is a stepwise approach.

Mr. PALLONE. All right. Mr. Rose?

Mr. ROSE. Yes, it would.

Mr. PALLONE. Dr. Davis?

Mr. DAVIS. And I agree with the phased-in approach as well.

Mr. PALLONE. Mr. Coukell?

Mr. COUKELL. Can I make a very brief response, Mr. Pallone?

Mr. PALLONE. Please.

Mr. COUKELL. The question was asked earlier, would serialization—

Mr. PALLONE. Yes, no or maybe. I am sorry.

Mr. COUKELL. Yes.

Mr. PALLONE. OK. Dr. Catizone?

Mr. CATIZONE. Two answers. Based upon existing technology, yes. Based upon the history of the industry in this regard, 25 years has not been enough time so they will probably say 10 won't work either.

Mr. PALLONE. All right. Mr. Berghahn?

Mr. BERGHAHN. Yes, I think it is possible.

Mr. PALLONE. OK. I mentioned in my statement, I have a lot of concerns with the Republican bill. We spent many months engaged with members on a bipartisan, bicameral basis discussing and learning about the problems associated with the security of our drug distribution system, but to put it simply, the draft just doesn't reflect where we landed at the end of those discussions or anything close, in my opinion, and the House Republicans, as I said, didn't consult with us before putting the draft out so I am disappointed, to say the least. But I would like to hear from some of you—I can't do everybody—on what you think is lacking in the bill. So let me start with you, Mr. Rose. What important aspects of a track-and-trace system is lacking or need improvement in the House draft?

Mr. ROSE. What we really need at this point in time is where are making our investments is a clear end game. We need to know where the goalpost is fixed. If we are making investments to put serialized numbers on our product and then also to exchange data, we want to make sure that the other parties in the supply chain are also using those numbers and using that information to verify

the product and the accuracy and the veracity of that product and then also the transactions associated with the product.

Mr. PALLONE. All right. Same for you, Ms. Gallenagh.

Ms. GALLENGH. Yes, I think that is correct. In our opinion, once we have serialization, there are many things that are possible with this but the one thing that differs between the past drafts is to not get to a clearly defined place or year date certain for traceability. We do think, though, that the bill draft does lay out the foundation to get there. The core elements again, as we have mentioned, and beginning with serialization and lot traceability, we do think that those are important steps that have to be taken before you get to that end phase.

Mr. PALLONE. OK. Mr. Coukell?

Mr. COUKELL. The current House draft immediately bans all State pedigree laws and doesn't replace them with anything for a period of many years, and it never gets to the second phase that we need to get to. It is like building a set of steps to your front door, building the first step now and having a plan to come back and put the second step on some time later.

Mr. PALLONE. Dr. Catizone?

Mr. CATIZONE. All the points that were previously made except it should not preempt State laws at this point because if it does so, there is no protection for the consumer. Two, I am confused by the argument about clear standards. They are needed. In 1998, NABP offered to develop national standards. Some people sitting at the table said the industry would do that. It is 25 years later. We still don't have those standards so I am not sure the standards are the barrier. The standards can be built and done so I believe clear direction, no delays, an implementation timeline and standards should be developed as quickly as possible.

Mr. PALLONE. Thank you. And finally, Mr. Berghahn?

Mr. BERGHAHN. Yes, I think one of the main concerns is the lack of the unit-level trace and the lack of requirements for people in the supply chain to use it. Without that, you really lose visibility on the product and you decrease safety.

Mr. PALLONE. Well, thank you. I am sorry I couldn't get to all of you but my time is limited.

I just wanted to reiterate that I am disappointed in the bill. The Senate released a draft last week that was an obvious attempt to address the views of Members on both sides of the aisle. It represents a compromise, and I regret that the House Republicans felt the need to sway so far from the good work that so many Members have put into this issue throughout the last year. So hopefully we can still come up with a good product. I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman and recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Dr. Davis, as you may have heard earlier, I represent a rural area with a lot of community pharmacists, and I want to focus your questions in regard to the e-pedigree program in California. How familiar are you with that program?

Mr. DAVIS. I have a cursory understanding of the specifics of it but again, I understand the concerns of my colleagues in that State as well through discussions.

Mr. GRIFFITH. Well, let us talk about that. Do you know how the small pharmacies, the small-town pharmacies in California are dealing with that?

Mr. DAVIS. We are still a few years away from pharmacies having to assume responsibility for their component of the program. But that being said, there are concerns surrounding the ability to absorb the costs and the labor associated with such a system.

Mr. GRIFFITH. Now, I understand you are not facing that, but have your colleagues in California given you some idea of what those costs would be for a small-town pharmacy?

Mr. DAVIS. Well, they range. Our problem is, our margins continually shrink at this point, and we have less and less to work with and still maintain our practices as our communities expect them to be maintained. That being the case, the estimates from colleagues range anywhere from thousands of dollars to having to remove employees from their work staff to replace them with this process. So the clear projections aren't intact at this point but there is a significant impact that is going to either impact the profitability and the ability for that business to support its community, or the profitability of the business being able to support its current employee structure.

Mr. GRIFFITH. And as a part of those concerns, are there concerns that some of the small-town pharmacies won't be able to survive with this cost?

Mr. DAVIS. Well, and that is always a question. I would say 99 percent of our technology costs over the past decade have been to comply with regulations and maintain technology and processes to comply by State and Federal regulations. That being said, we are worried that sooner or later our spending, our technology spending and our process spending, is going to outpace our ability to absorb it, and there will be doors that close unfortunately.

Mr. GRIFFITH. OK. So there is some concern that some of the pharmacies won't make it, and if that pharmacy happens to be in a small town and the next town over is on the other side of a mountain and 40 miles away, I am going to ask a question that I already know the answer to, but how does that impact the patient?

Mr. DAVIS. I come from a region very much like that, and what happens is, we see that patients are always trying to seek out the best care that they can at any given moment. That limits the patient's access to care and access to the best care that they can possibly get in their locations.

Mr. GRIFFITH. And in many cases, it is not just getting, you know, the prescription filled, it is that trust that has been built up. Sometimes you have—in fact, my pharmacist is the son of the pharmacist that we used when I was a child, and that trust has built up and so a lot of times there is a certain element of—I am I doing the right thing heading down this direction, or they will come in and they will just chitchat about what is going on in their health care, and particularly for senior citizens, they may be getting different prescriptions from different folks and sometimes having that resource is very valuable, is it not?

Mr. DAVIS. I agree, and most of my patients held me as a baby, so when I look them in the eye and I dispense medications or prescriptions to them, that is why this topic is so very valuable to me.

I need to know that I am taking care of their families much like they took care of mine through patronage and loyalty. So making sure that we provide safe, secure, and efficient medications for them on a regular basis is paramount. My dad always said always make the best decision for your patient and you have made the best decision for your company, and we are trying to do that in this day and age with this particular topic as well.

Mr. GRIFFITH. Yes, and I can't remember what the specifics were but I do know that in regard to one of my children, we went to get the prescription and the doctor looked at it and he said but isn't he also taking this, let me call your doc, and called the doc and they changed the prescription, and I think that is very valuable, and in rural areas, if you eliminate that community pharmacist, you have eliminated a valuable part of that tool. And so that is why I think it is proper that we move forward with a plan but also that we do it in a way that the community pharmacists don't get left out of the formula.

Mr. DAVIS. Thank you, sir.

Mr. GRIFFITH. I appreciate it, and yield back my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentlelady from California, Ms. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

Dr. Catizone, I would like to ask you about the role wholesale distributors play in the integrity of the drug distribution supply chain. I know that FDA has stated in its reports on counterfeit drugs that counterfeit drugs are most likely to be introduced as a part of a supply chain that involves multiple wholesalers. That is correct, right?

Mr. CATIZONE. Yes.

Mrs. CAPPS. Because of widespread abuses in the early 2000s, many States have tightened their licensure requirements. I believe Florida and California have especially strong licensure requirements, which they adopted to address specific problems that they had identified. However, there is, as you know, a wide variation in the rigor of different State requirements leaving many vulnerabilities in the system nationwide. My question is whether you agree that there is wide variation in State requirements for wholesale licensing and what has been the public health effect of these varying State requirements?

Mr. CATIZONE. There is variation but not as wide as I think people have reported. As an explanation, the primary wholesaler since the PDMA have done an outstanding job of cleaning up the industry and making sure the supply chain has its integrity and validity. We have seen problems with secondary wholesalers and pharmacies entering the picture. The patchwork among the States is being equalized through the accreditation program that we have, which has become a de facto national standard, and for States waiting to see what happens with California. If California moves forward, other States would follow suit and that would become a national standard across the board.

Mrs. CAPPS. OK. Given these differences, you say they are not as wide as we have been led to expect. Do you see any role for the FDA in setting federal standards for wholesale?

Mr. CATIZONE. Yes. What we talked about earlier, the need for standards, the FDA's role is critical to this process because the States have tried to put together a patchwork and we need that overseeing nationally.

Mrs. CAPPS. I get you. So thank you. And now I would like to get your views on the wholesale distributor licensing provisions of the House bill. It does require FDA to set licensure standards for all wholesale distributors. It also requires wholesale distributors to report annually to the FDA their name, address, dates in which they are licensed and any disciplinary actions that have been taken against them. The FDA would be required to publicly post the names of all wholesale distributors and the States in which they are licensed on their web page. However, the public would not be able to see the disciplinary actions that have been taken against any wholesalers that are on this site. In other words, that is not required in the bill. States would also be prohibited from having any licensure requirement except those established by FDA. Essentially, the new FDA standards could be seen as both a floor and a ceiling. Coming from a State like California with strong licensure standards, naturally I am concerned about that. So my question to you is whether you believe it is appropriate or necessary for the bill to prevent States from establishing or maintaining stricter standards or additional requirements to address local problems a particular State may have experienced. In other words, is this going to prevent individual States from addressing their own situations? Is there any public health benefit to the kind of system being described?

Mr. CATIZONE. The answer is yes, it will prevent, and we are sympathetic to the industry establishing some sort of uniform process, so we would support that, but the States need the discretion to act where there is a significant occurrence within their State, and we believe the bill would address that and even allow the States to be included in discussion. That would be critical.

In regard to the posting of information in response to the compounding issue, we will soon provide a listing of all the pharmacies in the United States, where they are licensed, what disciplinary action has been taken and whether or not they have been inspected. We can put that same system in place for wholesalers that we have accredited as well at no charge for the public.

Mrs. CAPPS. Thank you very much. I just have a few seconds, but Mr. Coukell, could you give us your opinion on these provisions in the House bill? I know it is going to be brief.

Mr. COUKELL. In the interest of time, I will second what Dr. Catizone said. We think national standards are very desirable. There is an important role for FDA to play there but we don't want to tie the hands of States at being able to respond to local conditions.

Mrs. CAPPS. I see a couple of heads nodding. Is this shared by anybody else on the panel? Could you indicate?

Mr. DAVIS. We agree as well. National standards, I think, would make it easier for pharmacists to be able to access and purchase and manage prescription products throughout the United States with some conformity.

Mrs. CAPPS. Thank you. Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentlelady and now recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. LANCE. Thank you very much, Mr. Chairman.

To Mr. Rose from J&J, I think New York recently proposed supply chain security legislation similar to standards in California. New York is obviously our neighboring State in New Jersey, and in fact, many pharmaceutical companies in the district I serve have employees from New York. If the California law were fully enacted and if New York follows suit we will have two highly populated States on opposite sides of the country requiring a varying degree of standard by which the entire industry from the manufacturer all the way to pharmacists must comply. You cite in your testimony a patchwork quilt of regulations, and I am interested in knowing how exactly would establishing a uniform tracking system ensure patient safety.

Mr. ROSE. Thank you for that question. What it would do is, it would give us security through the whole Nation. These labels that we are putting on our product, this product is sold throughout the State, or throughout the country, and we are talking about interstate commerce here. When we manufacture it, we don't manufacture for New York or California or Florida.

Mr. LANCE. You do it for the entire Nation.

Mr. ROSE. The entire Nation, and so as a result, we have this system in place. The entire Nation would benefit from this. All the citizens throughout the Nation would benefit from this system. It would provide a veil and umbrella over top of the supply chain, ensuring that we would keep counterfeit products out of the supply chain. It would give us another level of mechanism, another layer which we could prevent counterfeits from getting in the supply chain throughout the Nation.

Mr. LANCE. Thank you. Your testimony reflects a strong commitment to patient safety. How often are products compromised? Under the current system if a product is compromised, how is the manufacturer, J&J or others, alerted to an issue, and how do you address the problem?

Mr. ROSE. We are alerted to it in many ways. We may have received a call from a patient. We may hear from a doctor or a pharmacist. We have mechanisms in which we handle those calls, and we receive it and then we do an investigation of whether or not that is a counterfeit product or not. So we have mechanisms which we put in place to verify the authenticity of that product and then determine what the next steps might be.

Mr. LANCE. Thank you. Would anyone else on the panel like to comment on my questions? Yes, sir.

Mr. COUKELL. Just briefly. I don't think we know how common it is. There was a story in the newspaper this week. It was a tiny story—I think it maybe only ran in Chicago—about a pharmacist who had bought counterfeit drugs from China, I believe it was, and was dispensing them to patients and had been caught doing that. We don't know how common that is, and that is not to tarnish the industry. You know, 99.99 percent of them are good guys and the supply is generally safe but how common are these problems? I don't think we know.

Mr. LANCE. Would anyone else like to comment? Dr. Davis?

Mr. DAVIS. I think that again, the pharmaceutical industry, specifically, independent community pharmacists, rely on the rapport that we create with our patients, and it is very important for us to maintain that position. That being said, we take counterfeit medications, diverted medications and how we access and purchase medications in the industry very, very seriously. So that inherently adds a level of security that exists today.

Mr. LANCE. Thank you. Dr. Davis, let me say that I come from a small town and from a small family law practice, and we rely on a family pharmacy in a small town, and I know that there are many across America who rely on the good work of family pharmacies across this great country.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Utah, Mr. Matheson, 5 minutes for questions.

Mr. MATHESON. Thanks, Mr. Chairman, and I do want to thank all the stakeholders, more than just for being here today but there has been a lot of stakeholder involvement for a long time on this issue. I appreciate everyone spending the time to try to come up with a solution.

I have said it in my earlier comments: I think we need a uniform standard in place, a national standard, and it is really for two things. It is to ensure integrity of the drug supply chain at a national level and also alleviate operational burdens. It also is to prevent counterfeit or diverted product from reaching consumers.

So my first question is to Ms. Gallenagh. I was wondering if you could—you mentioned both the concern about operational burdens for stakeholders and the problem with counterfeit product hitting the market. Can you describe for me the operational challenges that your member companies would face in delivering product to their downstream partners across the country in a situation with no national standard and as different State laws go into effect?

Ms. GALLEENAGH. Absolutely. As you already know, HDMA members are primary wholesalers, so they purchase directly from the manufacturer in most cases and provide their products directly to the pharmacy and providers. The challenge with a 50-State approach, particularly when we start talking about not just pedigree but when we start talking about serialization and traceability really is the great unknown. If we are working on systems to be developed for California, for instance, that is one thing, but we operate national companies, much like the manufacturers. While we are not manufacturing product and we are not actually serializing that product, we will have to have the systems in place to be able to move it within our distribution networks, not just for the State of California but across the country. If we have a different standard for California than, for instance, in New York, which is also looking at this in their state legislature, then we have to segregate product according to region, and it makes it very difficult to know what types of systems we need to develop.

Mr. MATHESON. Do you have thoughts or can you elaborate on how a bad actor might circumvent more stringent State laws to introduce an adulterated product into a supply chain that doesn't have the national standard?

Ms. GALLENAGH. Sure. I think one of the problems with variation in State licensure was is one, the requirements. For example, some States don't choose to inspect wholesaler facilities when they are actually issuing licenses, and so then you end up with sort of fly-by-night actors or maybe substandard companies applying for and receiving licenses, and this has been shown to be a problem in States like Florida where when they did raise their licensure standards, they eliminated hundreds of bad actors and really not legitimate companies. I think that the other part of this, though, is also not just the variation in requirements but the variation in actually having to meet a standard bar. One kind of uniform set of requirements so that a bad actor can't move to the next State and get a license there, for instance.

Mr. MATHESON. Mr. Rose, in your testimony you described your company's experience with serialization of its products. You know, this is something that has been included in this discussion draft. Can you discuss the role that serialization plays in strengthening the integrity of the drug supply chain both in the near-term impact it could have as well as the role it would play in the longer term?

Mr. ROSE. Sure. In the near term, I think what it gives us is a capability that would be available in our product if we just looked at the discussion draft in its current form. You would have a serialized number on there that could then be verified, and that becomes important. I think what we would like to see as an end game is where every party in the supply chain is accountable for using that serial number and then also the information that is passed along with it. So we really believe that simple act of scanning that barcode becomes very, very important to help verify that package and ensure that it is the genuine package and then also the transactions that are associated with that package that can verify those transactions as well.

Mr. MATHESON. Thanks. Mr. Chairman, I will yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman. I got back just in time.

Mr. Coukell, I have some questions about the time frames set up in the House bill. As you know, it doesn't require much until about 5 years after the enactment. At that point it would only require manufacturers to serialize their product and to begin tracing their products by lot number, not unit level. I understand that actually getting a unit-level interoperable electronic system up and running, particularly on the federal level, will take some time and has many complications, but I am concerned the House bill doesn't start us on that path soon enough. In fact, it actually prohibits FDA from going forward with a unit-level electronic system in absence of new federal legislation. My question is, can you comment on this? And I am sure we can all agree that we want to ensure that industry has a reasonable amount of time to comply with whatever federal system we put in place but do we really need to wait until 2018 to even start on a lot-level non-electronic system?

Mr. COUKELL. Thank you for that question, sir. We absolutely share that concern as well as the view that the appropriate approach is to phase this in in a reasonable time frame that is something between California and what is proposed in the House draft,

and I think one of the big impediments to this whole area moving forward has been the lack of regulatory certainty. So leaving 10 years and still not having that certainty is likely to delay the field a very long time.

Mr. GREEN. Mr. Berghahn, do you have any thoughts on that too?

Mr. BERGHAHN. Well, I think that what would be important to consider is that many of the pharma manufacturers and the industry are already preparing today and putting systems in place to serialize an aggregate as we speak, and certainly allowing that to continue would be in the best interests of everyone. It doesn't mean that we are going to get to a National standard in anything resembling the timelines put in place in California but it certainly means that the basis is there. I mean, California is more than 10 percent of the population of the United States, so we could say if we allowed it to continue as scheduled that by 2017 10 percent of the product in the U.S. supply chain would be serialized.

Mr. GREEN. Mr. Catizone, how about you on that question? I am sure we all agree but do you really need to wait until 2018 even to get started on a lot-level non-electronic system?

Mr. CATIZONE. No, I think that is too long of a delay. I agree with the prior comments but also the caution, if this law preempts all existing State laws, there will be no oversight of the distribution system and the problems that we are seeing now will increase significantly so the medications you receive and I receive and others receive will not be safe if the State laws are all preempted.

Mr. GREEN. Well, I hope that we can work together to ensure we don't have unnecessary delays in implementing a federal system. Although I know that California may have 10 percent, but for a fellow with my Texas accent, we might want to have our own. But I do think we need across State lines regulation as quick as possible. And again, like any other regulation, if you know it is going to happen, you can capitalize it and prepare for it over a period of years and it looks like the bill may not be as aggressive as some of us would like. It sounds like some of the witnesses share it.

Thank you, Mr. Chairman. I will yield back my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for questions.

Mr. LATTA. Well, thank you very much, Mr. Chairman. Again, thank you very much for allowing me to participate in the hearing today. I really appreciate your willingness. And again, I want to thank the witnesses that are here today for their testimony today because we have to have input from everyone, which we have been doing for quite a while now, meeting with the stakeholders.

If I could start with Dr. Davis, and again, what we are looking at here, what we want is safety for the patients out there. We want to make sure that the supply chain is protected, that nothing is adulterated out there, and that when someone receives a medication, they know it is safe for them to take. And I think the chairman was talking about it a little bit earlier but if I could just ask you again, what is your view of having this phased in over time instead of something happening overnight? And I know that Mr. Griffith and Mr. Lance also kind of alluded to that in their questioning, but if I could ask you?

Mr. DAVIS. Again, I think our concern is of the level of complexity that occurs at the patient-to-practitioner level. We have a lot of very specific business rule questions surrounding lot-level versus unit-level serialization and tracking. What would happen if a patient had a prescription that we prepared for them, they decided that it was too expensive and we had already removed it from the packaging and the ability for it to be traced any further? How do we get that back into our drug supply? How do we take processes such as that to make sure that our businesses remain profitable and don't waste dollars on unused inventory, unreturnable inventory? How do we access the information and utilize the information, and how do we insert those processes in our current practices?

We are dependent. We are absolutely dependent on our technology vendors to provide us with the capabilities, and while we are wholeheartedly in to continue working with our partners to create a system in the United States and to maintain the system, we want to make sure that it is built in an efficient, affordable manner for us to implement in our communities.

Mr. LATTA. Thank you.

Mr. Rose, in your testimony, you state that this legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation. I am just kind of following up on that. How important is that phased implementation?

Mr. ROSE. We believe the phased implementation is important. The California law in many regards goes from zero to 60 very quickly so you go from serialization to this interoperable system. We really believe what is important here is to make sure that we have an approach that allows parties in the supply chain to prepare properly, to adopt these systems. As Dr. Davis mentioned, the pharmacies have some work to do, so do the wholesalers and the manufacturers. We still have a lot of work to do, as I indicated in my testimony. We have to give people some time to put those systems in place and make sure, to work out the interdependencies between the different stakeholders in the supply chain. That is where the real phased-in approach is really required is, how do we exchange data with the customers that we work with. It is very, very critical to do this, and it is not just the forward supply chain but it is also the reverse supply chain as well.

Mr. LATTA. Let me follow up with that. In your estimation, has California given you and the industry the guidance it needs for that operational clarity on how that law is going to work?

Mr. ROSE. We still are awaiting guidance on the interoperable system. Also, I think as I recall, and I will have to get back to you on this, but they have issued some guidance around grandfathering and I think they issued some guidance recently around inference, but we really do need to have much more guidance from them about their interoperable system, how that is going to work. That is a key piece right now.

Mr. LATTA. And I could turn real briefly, and I do mean briefly, Ms. Gallenagh, I believe we all share the same goal of improving the safety and the efficiency of the drug supply chain, as I mentioned earlier, that we want to make sure that everyone is safe out there. However, the argument has been made that what has been

proposed to date doesn't go far enough to satisfy all the elements of a comprehensive system that some had envisioned. Could you in practical terms talk about how the elements of this proposal would create a platform upon which to build future technologies?

Ms. GALLEENAGH. Absolutely. I think the intent of the bill, first of all, starts with what we traditionally call an interim pedigree step, essentially a direct purchase option and a full pedigree option across the board so that would be uniform across the country. It sets higher licensure standards to close those gaps across the States, and I think what we are all forgetting here when we talk about looking for the perfect solution is that this draft requires serialization for all products at the unit level regardless of where they are in the United States. I think that that alone sets a great foundation for what the industry can do with the product and with the systems once they are built. The lot traceability as a phase-in I think absolutely also lets us know how to work with that product and the serial numbers in a measured, responsible way and in a way that is practical for all of the supply chain partners.

Mr. LATTA. Thank you very much, Mr. Chairman, and my time is expired and I yield back.

Mr. PITTS. The Chair thanks the gentleman. That concludes the questions of our members. I am sure they will have additional follow-up questions and we will send them to you. We ask that you please respond promptly.

I would like to thank all of the witnesses for appearing today, two excellent panels, a lot of good information, a very important issue as we move forward, and I remind members that they have 10 business days to submit questions for the record. The members should submit their questions by the close of business on Thursday, May 9th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:49 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



“Securing our Nation’s Prescription Drug Supply Chain”

Statement for the Record
House Subcommittee on Health

Neil S. Alpert
President, LaserLock Technologies

April 25th, 2013



Chairman Pitts, Ranking Member Pallone, Jr. and members of the House of Representatives Committee on Energy and Commerce, Health Subcommittee, thank you for the opportunity to submit testimony to you for the record regarding the April 25, 2013 hearing entitled, "Securing Our Nation's Prescription Drug Supply Chain."

Like so many of history's great companies, LaserLock has evolved over time. Founded in 1999, we have been leading the development of cutting-edge authentication and anti-counterfeiting technologies. And, as this hearing indicates, the timing for such technologies couldn't be any more important.

In an age of global chaos, a major source of funding for terrorist groups and organized crime is counterfeiting. Every day, consumers unknowingly purchase counterfeit products from legitimate vendors, and perpetuate a global system of thievery and deception. And when these groups turn to the counterfeiting of pharmaceuticals and the American drug supply, they are not just eating away at someone's bottom line. More so, they are holding hostage the national security and public health of people in the United States and around the world.

Our shared mission is simple – to protect patients, health care providers and the companies that support them from the dangers of the global counterfeiting trade. By offering cost-effective solutions that authenticate products, pharmaceuticals, documents, and the supply chain more effectively than ever before, LaserLock continues to be a global thought leader in the fight to protect America against the proliferation of counterfeit goods, including pharmaceuticals.

LaserLock strives to create an environment where everyone has the ability to both verify the authenticity and provenance of any material. We believe that, counterfeiting and identity theft have become global problems affecting everyone. We don't want people to die from counterfeit medicines, foods or beverages. We don't want governments and or citizens held hostage by terrorists and organized crime. We don't want the woman who saved for five years to buy her first designer handbag to discover she has spent her savings



on a worthless counterfeit.

LaserLock is considered to be a leader in the anti-counterfeiting and authentication of products and packaging and has been for over a decade. We imagine a world where there are authentication solutions available to every American. We want everyone to be able to trust in the integrity and reliability of the products they purchase and use. We believe this will be a better world for all of us, and we commit ourselves to realizing this vision. We believe the best way to predict the future ... is to invent it.

Problems in the Pharmaceutical Supply Chain

The World Health Organization estimates that 1% of all drugs in the United States are counterfeit. With the Kaiser Family Foundation estimating the number of prescriptions filled each year in the United States at around 3.7 billion, this translates to roughly 37.6 million prescriptions filled annually with counterfeit pharmaceuticals. This places nearly every American consumer of prescription drugs risk of consuming either an ineffective or harmful medication. This needs to be stopped and can be done so with three easy steps utilizing existing solutions: authentication technology, mobile devices and authentication databases. Consumers should be confident that when they purchase pharmaceuticals that their medication works as advertised.

Counterfeit drugs are dangerous by their very nature: they are not produced under safe manufacturing conditions and they are not subject the same regulatory scrutiny as legitimate medications. Fake pills can look identical to their genuine counterparts but may contain an incorrect amount of the active ingredients or no active ingredient whatsoever. Additionally, noxious ingredients have also been found in counterfeit drugs with fatal consequences. For example, in October 2012 counterfeit ingredients found in steroids from a compounding pharmacy near Boston killed 11 people with fungal meningitis and sickened more than 100. While the U.S. pharmaceutical distribution system is among the safest in the world, the incidents of counterfeiting continue to increase annually. One of the reasons is that as technology



improves, counterfeiting becomes easier. Unfortunately, counterfeiters only have to reproduce an authentic looking package; what's inside doesn't matter to them.

Counterfeit pharmaceuticals not only affect the consumer, but have also produced a wide range of negative effects on the pharmaceutical industry itself. These typically manifest as lost revenue, decline in brand value, lower incentives to invest in research and development, and higher protection and auditing costs. The lack of data available to researchers of this problem prevents any strong quantifiable insights at the industry or company level. Nonetheless, what data is available does suggest that the problem threatens the financial health and competitiveness of the U.S. pharmaceutical industry.

The U.S. Customs and Border Protection Agency (CBP) has reported that between fiscal years 2004 and 2009, the domestic value and seizures of pharmaceuticals increased overall. According to Pfizer, the factors that contribute to the rise of pharmaceutical counterfeiting are unregulated wholesales and re-packagers in the supply chain, the growth of Internet pharmacies, advances in technology that make counterfeiting easier and the increased importation of prescription drugs from abroad.

In the past, counterfeits were confined to illegal or unauthorized channels of distribution. More recently, legitimate channels of distribution in the U.S. and other countries with advanced economies have been increasingly infiltrated by counterfeits.

As has been exhaustively covered in this hearing, the pharmaceutical supply chain lacks a reporting structure capable of comprehensively documenting the movement of a product from the producer to the end consumer. This lack of documentation along the supply chain creates a blind spot each time the product changes hands. These blind spots are precisely what counterfeiters look to exploit. Introducing an industry-wide system that holds all participants accountable within the distribution network is needed to deter and end unnecessary public health problems and economic losses.



Counterfeiting is widely acknowledged as an attractive funding ploy for sophisticated criminal organizations and global terrorism. Pharmaceuticals are easy to transport and carry much lighter criminal penalties in the event they are detected.

At a time when counterfeit pharmaceuticals are flooding the global market, the pharmaceutical industry, public health advocates, and security professionals are trying to educate the public about the need for caution when purchasing their medicines and the importance of closing our borders to these potentially dangerous products. We agree with the subcommittee that a uniform code of standards needs to be applied and industry alone cannot dictate how to deliver it, yet serialization, or the concept of uniquely identifying medicines at the unit level (vs. batch or lot), while required for resilient track and trace capabilities, is not sufficient to significantly reduce counterfeiting. When serialization is implemented through the use of overt markings, such as visible barcodes, Datamatrix or QR codes, we are simply providing the counterfeiter with precisely the information they need to perpetrate their deception.

We are convinced that by combining covert and overt anti-counterfeiting techniques it is possible to implement a comprehensive system that:

- Is dynamic, flexible and adaptable – new anti-counterfeiting characteristics can continuously be added and updated
- Incorporates overt characteristics that provide the ‘visible’ information required by broad numbers of stakeholders, patients, etc.
- Incorporates covert characteristics that allow ‘restricted knowledge’ to be compartmentalized and made available exclusively on a “need to know” basis
- Incorporates covert characteristics which can be linked to the overt characteristics, but would rely on ‘restricted knowledge’ for authentication, thereby creating significant barriers to compromise by attackers.



We believe the only way to implement a comprehensive solution for securing our nation's prescription drug supply chain is through the innovative use of both overt and covert anti-counterfeiting techniques.

Designing a More Secure Supply Chain

It is our conviction that securing the supply chain requires several key technological elements and multiple layers of authentication. As the United States moves toward a uniform national policy of tracing pharmaceuticals through the distribution system, such a system should incorporate the most recent developments in authentication technology and advances in cloud computing.

As a system, a secure, modern, prescription drug supply chain should utilize available technologies to solve the entire problem of counterfeit pharmaceuticals, of which we assert that serialization is just one piece. In order to be effective it must protect both the health and safety of the American people while at the same time not place any unnecessary financial or logistical burden on manufacturers, wholesale distributors, pharmacies and re-packagers. Counterfeiting is easy to do; the solution to prevent it should be just as easy.

The prescription supply chain must contain elements that protect the serialization markings themselves from being counterfeited. If something can be seen, it can be copied. It is also critical that the system allows consumers to walk into any of the 60,000 pharmacies in the United States and verify that the drugs they are buying are authentic. This is fully achievable with existing technology designed specifically to secure supply chains.

Integrating Technologies

We believe there are three technological components to designing the ideal tracing system:



-
- Authentication Technology
 - Mobile Devices
 - Authentication Databases

In combination, these technologies will work with each other to create a simple, cost-effective and easy to integrate solution to securing the prescription drug supply chain.

Authentication Technology

Innovative anti-counterfeiting and authentication technologies will be critical to designing a secure system. Packages must be marked with both overt and covert solutions to create multiple layers of security. We believe utilizing both solutions provides the best way to mitigate the risks of counterfeiting. Security inks that can be seamlessly integrated into the printing process are the best approach to doing this. A single ink that contains multiple security characteristics would be the best way to thwart and confuse counterfeiters.

As this legislation proposes, the key to tracking pharmaceuticals across the entire supply chain is to serialize each lot with a standard numerical identifier, which can be represented in a variety of markings including barcodes and QR codes. It is critical that these serialization markings are protected against counterfeiting, since they become the front line of defense in identifying real or counterfeit prescription drugs. Ideally, these markings must be printed covertly on the package, invisible to the human eye but able to be read by the proper optical equipment.

To serialize each package as a solution is insufficient. If a counterfeiter were able to infiltrate the serialization data, it would in theory be able to pass off counterfeit drugs as authentic as long as they were entered into the supply chain first. However, if the serialization markings are printed with a secure covert ink that could be read only by high-tech optics built into everyday smartphones, then it would be impossible for an organization without access to such technology to counterfeit the serialization, even if they were to come



into possession of the necessary data. By utilizing invisible technology, you take that ability away from the counterfeiter, creating a barrier to the data.

Mobile Devices

While it is generally recognized that the hologram has lost its status as the premier anti-counterfeiting technology, its value as a technology was that it required no external device to activate it. It is difficult to use security inks described above without external devices to activate or read them in the same way. Thus, a device would be needed. Such a device should be handheld, possess image gathering capabilities, communication and data transmission capabilities. While there are a number of devices that fit this category, smartphones have penetrated the U.S and global markets to the point of ubiquity and utilizing them would eliminate the need to buy and bring costly equipment into the supply chain. The optics capability to read the covert markings described above would be integrated with permission levels on any smartphone and the simplicity of such a system would be astounding.

Authentication Database

To create a resilient solution that delivers complete and accurate authentication information requires communication. There are 2 primary drivers behind this conclusion:

1. Restricted Knowledge – the specific information about what covert characteristics are being used, how they are being used and what information they contain – can be securely stored in the cloud and released on a strictly “need to know basis” and only to other authenticated systems (for instance systems printing the marks and system inspecting the marks).
2. During authentication of the pharmaceutical, the information that is returned to the user can be determined based on who the user is. A patient, for instance might be told the name of the medicine, the manufacturer and the expiration date. A distributor, could additionally be provided batch #, lot #, data of manufacture, etc.

Another key to improving the resiliency of the system and specifically for guarding against replay attacks, where a criminal makes a exact copy of the product packaging, including serialization information is to maintain



information about the state of a product (manufacture, distribution, dispensing, consumption). A centralized secure cloud can insure real-time access to information that can be correlated with other data, such as date/time, location and individuals performing authentication. Analytics can be easily applied to detect anomalies or discrepancies associated with individual items.

The cloud service can also facilitate compartmentalization of information. Product information can remain with the manufacturer, distribution information with the distributor, etc. The cloud service focuses on the authentication and management of the unique identifiers themselves, not the underlying product specific information.

Minimizing Disruption

The key to designing a secure, modern, prescription supply chain system that can be implemented in the real world is minimizing the disruption it would cause to the existing pharmaceutical supply chain. An ideal system should be able to be seamlessly integrated into the current pharmaceutical packaging and manufacturing process. This would leverage existing production equipment and processes and minimize implementation costs.

Both security inks and mobile devices play a crucial role in minimizing such disruption. Inks can be integrated directly into the printing process and would require no additional steps, minimizing costs other than the cost of the ink and the services of a third party logistics provider to provide the form of the markings. Nothing would need to be attached separately to the packaging and so there would be virtually no disruption in the current packaging production process.

Similarly, if the system were to run on a smartphone, a secure application could be developed with differing levels of access across the supply chain that would prevent the need for manufacturers, wholesale distributors, pharmacies and re-packagers from having to make massive purchases of equipment.



Universal Availability

The final key component of an ideal track and trace system is its accessibility to both the supply chain and the consumer. We believe it is paramount that consumers have the ability to authenticate their prescription. Again, the ubiquity of smartphones plays a crucial role in allowing the same technology used to track and trace a pharmaceutical product through the supply chain to also be used by the consumer to verify that their prescription is authentic. By utilizing smartphones, you provide every consumer with the ability to easily authenticate their medicine at the point of purchase, increasing their own degree of confidence in the drugs that they buy. By utilizing smartphones in the battle against counterfeiters, for the first time this gives the consumer the advantage.

A mobile application would be downloaded to any given smartphone. One version of the application would be for those in the supply chain, allowing them to read covert markings and transmit the tracking information to the secure cloud at each step along the chain. The second version would be widely available to the public, and would read the same marking, but would simply alert the consumer of the product's authenticity. We see this as a fundamental right of all consumers to be able to verify the authenticity of their pharmaceuticals.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores
For
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
Hearing on:
“Securing Our Nation’s Prescription Drug
Supply Chain”
April 25, 2013
10:00 a.m.
2322 Rayburn House Office Building

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*NACDS Comments to the House Energy and Commerce Health Subcommittee
Hearing Held on April 25, 2013
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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for consideration of our statement for the hearing “Securing Our Nation’s Prescription Drug Supply Chain.” We look forward to our continued work with you on issues related to the security and integrity of the U.S. prescription drug supply chain.

NACDS commends the Committee for their efforts. This statement addresses the following matters:

- The necessity of enacting a national approach to securing the Nation’s drug distribution supply chain now.
- The chain pharmacy industry support for the work of the Pharmaceutical Distribution Security Alliance (PDSA).
- Chain pharmacy policies for the security of the U.S. drug distribution supply chain.
- Chain pharmacy comments on the recent discussion draft released by the Committee.

U.S. DRUG DISTRIBUTION SUPPLY CHAIN IS SAFE

The United States prescription drug distribution system is recognized as one of the safest and most secure in the world, if not the safest. The Food & Drug Administration (FDA) has stated that drug counterfeiting is rare in the U.S. drug distribution system due in large measure to the extensive scheme of federal and state regulatory oversight, and steps already taken by pharmacies, drug manufacturers, and wholesale distributors to prevent counterfeit drugs from entering the U.S. drug supply.¹

NACDS and the chain pharmacy industry are committed to partnering with policymakers and supply chain stakeholders on viable, effective strategies to further enhance the safety and security of the U.S. prescription drug distribution supply chain. Our members have invested significant resources and efforts towards this goal, including changes in purchasing practices

¹ See <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM272150.pdf>; *FDA Preliminary Report: Review of Counterfeit and Diversion Criminal Case Information*, September 2011.

and actively supporting legislation enacted in a number of states that strengthened the U.S. supply chain integrity. We have also supported increased fines and penalties for violations of these state laws. Our members have seen marked improvements in the security of the drug distribution supply chain since the adoption of these initiatives and state laws. Nothing is more important to our industry than the health and safety of our patients.

We urge policymakers to consider approaches to enhance supply chain integrity that are feasible and workable for the supply chain, and that recognize the importance of allowing a stepwise approach that uses feasible and tested approaches for adding enhancement to supply chain integrity. We do not support approaches that mandate the use of untested, costly requirements that would disrupt, rather than enhance, supply chain security. These proposals would add billions in additional costs to the healthcare system and take time and resources away from pharmacies' ability to provide care to their patients.

NACDS' POLICIES

We believe that the security of the U.S. prescription drug distribution supply chain requires the commitment of all supply chain stakeholders working together to ensure the security and integrity of the supply chain; any measures must be tested, implementable, feasible and achievable. To that end, NACDS is a member of the *Pharmaceutical Distribution Security Alliance* (PDSA), a coalition of supply chain stakeholders including drug manufacturers, wholesale drug distributors, third party logistics providers, their national associations, as well as pharmacies and their national associations. NACDS is pleased to be a member of PDSA and to work with other supply chain stakeholders on efforts to enhance supply chain integrity.

NACDS supports measures that include providing uniform federal requirements for wholesaler drug distributor licensure that is implemented by the states, evaluation and pilot projects to inform and phase in any changes to supply chain security, and federal preemption to establish a uniform national solution for supply chain security. These policies will lead to a national uniform supply chain integrity platform rather than the current patchwork of state laws. A patchwork of state requirements is unworkable and has the potential to hinder the timely and

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efficient distribution of drugs across the nation. Moreover, a national approach provides the benefits of blocking unscrupulous entities from “gaming” the system by moving across state lines in search of less stringent laws.

COMMENTS ON DISCUSSION DRAFT

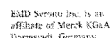
We applaud Representatives Latta and Matheson, as well as the full Committee, for the comprehensive discussion draft legislation. In particular, we support one national standard as promoted by PDSA and recognized by Congressmen Latta and Matheson. A comprehensive, practical approach would enhance safety and efficiency, and minimize inconsistencies among the states.

Along with PDSA, we support enhancing the licensing standards of wholesale distributors. To ensure that bad actors are not allowed to enter the prescription drug supply chain by becoming licensed in the state with the least stringent requirements, we agree with the Committee draft with the establishment of a national floor for rigorous state wholesale licensure requirements. As a member of PDSA, we support their proposal for lot-level identification of prescription drug packages. We are pleased that you have included all of these elements in the Committee’s discussion draft.

As proposed by the discussion draft, the next phase of supply chain security would be best informed by pilot projects, routine public meetings, and well-designed studies. Without the critical information that would be gleaned from these projects, meetings, and studies, there would be a great risk of mandating systems and technologies that are not feasible, mature, or scalable. We must ensure patient access to critical lifesaving medications without imposing unnecessary or unworkable burdens on the mechanisms that deliver those medications to patients.

CONCLUSION

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.

 EMD Serono EMD Serono Inc. is an
affiliate of Merck KGaA,
Darmstadt, Germany

November 7, 2012

Re: Comments on October 24, 2012 Draft Language (Supply Chain Safety)

To Whom It May Concern:

Thank you for the opportunity to comment on the most recent legislative proposal to implement a nationwide supply chain safety system for pharmaceuticals and biologicals. EMD Serono is pleased to see a significant level of compromise, particularly related to Phase Two of the process, reflected in the current draft and appreciates the commitment and efforts of the working group and interested stakeholders in this discussion. We firmly believe that a strong supply chain safety standard is critical to help protect patients from the impact of counterfeiting and diversion, and we have seen the benefits of a robust track and trace mechanism firsthand.

EMD Serono is the U.S. affiliate of an international biopharmaceuticals company with products to combat the effects of complex conditions like multiple sclerosis, HIV and infertility. The products are highly specialized and, as such, are subject to counterfeiting and diversion by illegitimate parties in the U.S. and around the world. For this reason, we have been active on the issue of supply chain safety for over a decade and developed a comprehensive track and trace model that allows us to follow certain products from the manufacturing line to the pharmacy.

Our experience has taught us that having the ability to track our products to the end dispenser by enabling unit-level traceability is imperative to the effectiveness of this system. Like many involved in the prescription drug sector, we believe that a nationwide supply chain safety standard is optimal for enhancing the integrity of products consumed by American patients. We also believe that to reduce risk of counterfeit or adulterated prescription drugs from entering the U.S. supply chain, the pathway for unit-level tracking and aggregation to support operational needs must be timely and must include all of the stakeholders in the product distribution chain. While the current proposal does include some improvements in this regard, there are additional changes that must be made to support patient safety.

In 2002, EMD Serono implemented a secured distribution model including a track and trace program for one of its products and in 2010 incorporated a second. Shipments of these products are restricted to contracted pharmacies that participate in this program. Each unit is uniquely serialized and can be tracked to the pharmacy level.

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November 7, 2012

Since the California Board of Pharmacy proposed the electronic pedigree and serialization legislation in 2004, EMD Serono has been diligently working on implementing an interoperable system for all products using the GS1 standards and initiating pilot programs with wholesalers. Given the ongoing stakeholder investment in compliance with the California model and the quickly approaching effective date for the related requirements, it is critically important that action at the federal level consider that momentum and investment. At a minimum, a federal approach to supply chain safety should maintain the standards that exist in the California law and, where possible, incorporate the work already being done in California into a nationwide framework. Failure to do so would result in a step backwards on public health and put significant industry efforts to improve supply chain safety in a precarious position.

While we appreciate the inclusion of a more definite timeframe and process for unit-level tracking in Phase Two, we also remain concerned that the timeframe contemplated by the draft is unnecessarily long and deviates significantly from the traditional rulemaking process included in the Administrative Procedure Act. In fact, if Congress chose to enact the longer time options bracketed in the draft, it would be over 15 years before unit-level tracking is incorporated in the U.S. supply chain safety requirements. Given the existing technology and standards available, and the work currently underway to comply with the CA state-mandated supply chain requirements coming online in the next few years, the inclusion of such an extended timeline is simply wrong for patients. Even where those state requirements may be pre-empted by federal law, the movement towards unit-level tracking around the globe means that the technologies and standards needed to implement the system contemplated in Phase Two of the draft are readily available, and many stakeholders are using those technologies today to distribute pharmaceuticals abroad. As such, it seems as though the extended timeline options offered in the draft document prevent implementation of a system that can reasonably be started today.

Specifically, we would recommend a Phase Two timeline that provides federal standards for unit-level tracking that would be effective in 2021. This can be achieved by modifying a number of elements included in the current proposal draft, as illustrated in this letter. Examples of these modifications include the following:

- Allowing FDA to run the specified pilot programs concurrently with the effective date of the legislation beginning in 2014. There is no need for a two-year delay in starting these pilots, especially given that there are a number of manufacturers, wholesalers, 3PLs and dispensers who are already actively engaged in unit-level tracking and could offer their expertise and existing operations in a pilot format immediately.

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- Elimination of annual public meetings as required in the current draft. These meetings are not necessary given the ample opportunity that stakeholders will be afforded in the rulemaking process and elsewhere. It is not clear that these meetings will generate any additional insight that could not be offered using existing channels of communication, and they are likely to create additional hurdles and delay in the development of a unit-level tracking standard. Likewise, movement forward with a unit-level tracking standard should not be conditioned upon premature study requirements given the wide array of information that will be available through pilot projects and global supply chain efforts underway by industry stakeholders.
- Reduction of the extended timeframe for development and enactment of regulations related to Phase Two, including the two year delay between issuance of final regulations and effective dates of final regulations (or application of default provisions). The federal rulemaking process that currently exists under the Administrative Procedure Act includes ample time for notice and comment by stakeholders, and it is commonly used for implementation of new federal requirements that exceed the scope of the changes included in Phase Two. There is no need nor is there justification for creating a new rulemaking process for implementation of unit-level tracking.

In the absence of a federal law including pre-emption of state supply chain requirements, the pending system being implemented in California will be effective for all participants in the distribution channel by 2017. The extended Phase Two timeline option included the draft will put federal rules into effect as late as 2028 and make them applicable to a more limited subset of distribution channel participants. Enacting a federal framework that requires federal regulations to take effect no later than 2021 presents a reasonable compromise between these two options and provides the time needed to ensure that impacted stakeholders have sufficient time to prepare for and develop the systems necessary to comply with those federal regulations.

In addition to our recommendations on the timeline for Phase Two, we also encourage Congress to ensure that the proposed supply chain safety system is applicable to all relevant parties in the pharmaceutical distribution process. While the draft does include significant requirements for manufacturers, wholesalers and 3PLs, we are concerned that it does not contain adequate requirements for the parties dispensing products to patients, such as pharmacies. Pharmacists must be part of the verification process for unit-level tracking to be successful- they are the end link to patients and the direct distribution point for a major portion of the U.S. pharmaceutical supply. Most importantly, we believe there are basic standards that pharmacists can achieve with reasonable effort and little monetary investment, making compliance in the near term more than feasible.

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Similarly, we strongly believe that Congress should exercise caution in the creation of waivers and exceptions targeted towards arguments of economic hardship. While all stakeholders recognize that an adequate supply chain safety system will require additional investment, it is important to understand that all points in the distribution channel must participate in that system in order for it work effectively. As a company that developed an evolving unit-level tracking system over the past decade, we have learned that it is possible to deploy effective technologies that require relatively modest investment. Moreover, our experience taught us that aside from the public health benefits of these efforts, there is business value for stakeholders. .

As noted previously, EMD is pleased to see the inclusion of a concrete pathway forward for unit-level tracking, and we especially appreciate the inclusion of a default standard should the specified rulemaking process fail to produce final Phase Two regulations by the required deadline. However, we recommend that the proposed default provisions be strengthened and clarified to ensure that the outcome of the Phase Two process does not result in a step backwards from where the supply chain safety effort would have been in the absence of the attempt to enact a federal standard.

As such, the language related to the default provisions must clearly require, at a minimum, the following:

- Unit-level tracking for all downstream, change of ownership transactions involving eligible products
- Appropriate and comprehensive grandfathering protections to ensure fairness (similar to those protections developed by the State of California)
- Aggregation of product information as necessary to reduce operational burden for unit-level reading on downstream partners.
- Inclusion of an adequate “pedigree,” including a comprehensive transaction history, as appropriate with the transfer of ownership of a product

In addition to the general comments outlined above, we would also like to offer more detailed suggestions on specific provisions of the draft legislation. For ease of use, these suggestions are detailed on a section-by-section basis in Attachment Two to this letter.

EMD Serono strongly favors the creation of a nationwide standard for supply chain safety. Establishment of one uniform system not only allows for more efficient compliance from the business perspective but also enables the highest level of safety for patients by potentially creating an interoperable system rather than relying on a patchwork of standards. However, a uniform standard must not be achieved at the expense of the strength of a track and trace system. Moreover, we cannot support establishment of a nationwide standard that would lessen the requirements existing in current state law. Although we understand the desire to pre-empt states like California from moving forward with state requirements when a national standard is preferable, pre-emption is not acceptable unless the basic standards in states like California are maintained, or ideally, improved.

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We urge you to continue working on this proposal to accelerate the unit level tracking and include all of the elements necessary to the process of securing the U.S. drug supply. We also urge you to refrain from pre-empting states like California from moving forward unless the prevailing policy is as strong, or stronger, than those state laws.

Thank you for your time and efforts in this process, and we remain willing to offer technical advice to the committees about all facets our program, including implementation of a unit level verification system. If you have any questions, please do not hesitate to contact either David Nichols at (202) 626-2594 (David.Nichols@emdserono.com) or myself at (202) 626-2598 (Lynn.Taylor@emdserono.com).

Sincerely,



Lynn Taylor
Vice President, Government Affairs

cc: Chairman Tom Harkin
Ranking Member Mike Enzi
Chairman Fred Upton
Ranking Member Henry Waxman
Senator Lamar Alexander
Senator Michael Bennet
Senator Richard Burr
Senator Charles Grassley
Senator Diane Feinstein
Senator Sheldon Whitehouse
Representative Brian Bilbray
Representative John Dingell
Representative Jim Matheson
Representative Frank Pallone

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ATTACHMENT: Additional Specific Comments

Section 2

Section 581 (Definitions):

- A number of the relevant terms are similar or identical to terms being used in the context of the California state supply chain requirements, and the stakeholder community has been active in achieving a consensus around a number of those terms. As such, we recommend that Congress consider adopting the definitions used for similar terms under California law where they are available and appropriate. For example, the terms “manufacturer,” “repackager,” and “third party logistics provider” are all defined in California statute in a comprehensive fashion, and those definitions could be appropriately used in the federal context as well.
- The definitions of “illegitimate product” and “suspect product” should incorporate language similar to that found in CA statute, which specifies that, “ If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge.
- The exemption from the definition of “transaction” specified in subparagraph (xii) should be deleted because this type of transaction is indeed a change of product ownership and should not be considered exempt.
- The “transaction information” definition should also include product identifier information as a requirement in Phase Two.
- The “transaction statement” should be defined as a certified document (such as a signed transaction statement). The definition should also specify that the signature is a certification under penalty of perjury from a responsible party of the source of the product that the information contained in the pedigree is true and accurate.
- Section 582 (Requirements)
- The bracketed language included in section a(1) should be retained.
- The two years specified for publication of standards under section a(2) is too long. Such standards currently exist and are widely used and, therefore, there is no need to wait to two years before publishing the standard.
- The availability of a waiver for “undue economic hardship” found at section a(3)(A)(i) should be removed because it is not needed nor is it sufficiently defined. If removal is not possible, the term “undue economic hardship” should be qualified and defined to provide more clarity on the standard for a waiver.
- The language at a(3)(A)(ii) should be amended to include more clarity around the process that the Secretary may use to determine exceptions.

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- Section a(5) should be significantly revised to reflect an appropriate grandfathering mechanism, and the Secretary should be required to develop regulations within one year. We recommend this language incorporate the standard that is reflected in California statute, which provides the following:
 - (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.
 - (2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.
 - (3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.
- Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.
- The timeframe for the manufacturer requirements found at (b)(1)(A) should be revised from one year to six months.
- The bracketed language at (b)(1)(A)(ii) should read “upon each transaction”
- The language at (b)(1)(A)(iii) should be revised to require information be maintained for not less than 7 years.
- The language at (b)(1)(A)(iv) should read 18 months.
- The manufacturer requirement found at (b)(1)(A)(iv) should be amended to include aggregation in addition to the package and homogenous case requirement.
- The timeframe included in (b)(2) should be 3 months.
- The timeframe included in (b)(3)(A) should be 18 months.
- The timeframe included in (b)(3)(A)(ii) should allow 72 hours after receiving the verification request rather than 24 hours to account for requests that occur over a weekend, etc. In the alternative, the statute could reference business days rather than hours.
- The language found at (b)(3)(D) should be revised to accurately reflect manufacturer practices. Typically, manufacturers do not redistribute product that has been returned, although wholesalers do frequently redistribute product that has been returned to them.
- The timeframe included in (b)(4)(A) should read 6 months.
- The timeframe included in (b)(4)(C) should read 7 years rather than 2 years or 10 years.
- The timeframe included in (b)(4)(D) should read 72 hours rather than 24 hours.
- The timeframe included in (b)(5)(A) should be 6 months.

Comments from EMD Serono
November 7, 2012

- The language at (b)(5)(A)(ii) should be clarified to provide more explanation of what constitutes “reasonable steps.”
- The timeframes included in (b)(6) should read 72 hours rather than 24 hours.
- The timeframe included in (c)(1)(A) should read 6 months.
- The language at (c)(1)(A)(ii) should read “upon each transaction.”
- The timeframe included at (c)(1)(A)(iii) should read 7 years rather than 2 or 10 years.
- The timeframe included at (c)(1)(A)(iv) should read 30 months.
- We recommend the use of Option 4 language under the saleable returns standard found at (c)(1)(B)(i).
- The language at (c)(1)(B)(ii) should be amended to specify that all transaction history should be included with returns.
- The timeframe included at (c)(2) should read 3 months.
- The timeframe included at (c)(3) should read 30 months.
- The timeframe included at (c)(4)(A) should read 6 months.
- The timeframe included at (c)(4)(C) should read 7 years.
- The timeframe included at (c)(4)(D) should read 72 hours.
- The timeframe included at (c)(5) should read 6 months.
- The timeframe included at (c)(5)(C) should read 7 years.
- The timeframe included at (c)(6) should read 6 months.
- The timeframe included at (c)(6)(C) should read 72 hours.
- The timeframe included at (d)(1)(A) should read 6 months.
- The language at (d)(1)(A)(ii) should read “upon each transaction.”
- The timeframe included at (d)(1)(A)(iii) should read 7 years.
- The timeframe included at (d)(1)(A)(iv) should read 3 years.
- The language regarding saleable transactions at (d)(1)(C)(i) should be amended to require that the information under subparagraph (B) be included.
- The language regarding nonsaleable transactions at (d)(1)(C)(ii) should be amended to require that the information under subparagraph (A)(i) be included.
- The timeframe included at (d)(2) should read 3 months.
- The timeframe included at (d)(3) should read 3 years.
- The verification language at (d)(3)(B)(ii) should be amended to delete the 10% verification requirement and require every product to be verified at the unit level that is suspect.
- The timeframe included at (d)(4)(A) should read 1 year.
- The timeframe included at (d)(4)(C) should read 7 years.
- The timeframe included at (d)(5) should read 1 year.
- The timeframe included at (d)(5)(C) should read 7 years.
- The timeframe included at (d)(6) should read 1 year.
- The timeframe included at (d)(6)(C) should read 72 hours.
- The timeframe requirements for Third Party Logistics Providers (3PLs) found in section (f) should be aligned with the timeframes for manufacturers. Generally, we recommend selecting the shortest timeframe included in the bracketed options.

Please note: Our comments on the provisions of Section 3 are included in the body of our comment letter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 19 2013

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the April 25, 2013, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Securing Our Nation's Prescription Drug Supply Chain." This letter provides responses for the record to questions posed by one of the Committee Members, Congresswoman Ellmers, which we received on May 24, 2013.

If you have further questions, please let us know.

Sincerely,

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking member

We have restated the Member's questions below in bold, followed by our responses.

The Honorable Renee Ellmers

- 1. Dr. Woodcock, you mention that a breach in any point of the supply chain could lead to dangerous outcomes for patients. How critical is identifying and licensing all entities that manufacture, store, transport and distribute drugs in realizing visibility and security in the supply chain? And can you elaborate why?**

It is essential that there is transparency and accountability in the drug supply chain. An important element of this is knowing the legitimate players in the supply chain that manufacture, store, transport, and distribute drugs and ensuring that they are licensed or otherwise accountable to Federal and state officials. This allows FDA to take swift action against those who are not legitimate and who may be bad actors. It is also important for other supply chain stakeholders to know who are the legitimate players and only do business with those entities. This creates a closed drug supply chain that further ensures the security of drug products and minimizes the chances of patients receiving an unsafe or ineffective drug.

- 2. We all know that the most important goal of pharmaceutical supply chain track and trace legislation is to ensure that medicines are safely delivered to patients in North Carolina and the rest of the country. In the wake of recent high profile prescription drug counterfeiting cases in the U.S., can you share with us a summary of the discussions that you have had with patient groups regarding the importance of supply chain safety to combat these types of cases from occurring in the future?**

Because recent incidents have involved injectable drugs purchased directly by medical practices from foreign or unlicensed suppliers, we have been focusing on educating the health care community about the risk of receiving drugs that may be counterfeit, contaminated, improperly stored and transported, ineffective, and/or unsafe. Medical practices that purchase and administer illegal and unapproved medications from foreign sources are placing patients at risk and potentially depriving them of proper treatment.

To date we have not met with specific patient groups; however, we have issued public alerts and notices through FDA's MedWatch system about these incidents and the risks involved. Many patient organizations subscribe to Medwatch and further distribute these alerts and notices to their members.



June 17, 2013

The Honorable Joseph Pitts
Chairman
House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts:

Thank you for the opportunity to testify before the House Energy and Commerce Subcommittee on Health on April 25, 2013 at the hearing entitled "Securing Our Nation's Prescription Drug Supply Chain." I have attached my response to the Questions for the Record.

HDMA supports H.R. 1919, the Safeguarding America's Pharmaceuticals Act and believes that a national approach to pedigree and traceability is the right approach to further strengthen our pharmaceutical supply chain, help ensure safe, efficient delivery of medicines and protect patients from the threats associated with counterfeit and diverted products. This legislation contains the core elements necessary to establish a comprehensive, practical framework that increases safety, continues to promote efficiencies and minimizes inconsistencies among competing state requirements.

Thank you for your leadership on this important issue and we look forward to continuing to work with you and your staff as this issue moves through the legislature.

Sincerely,

A handwritten signature in dark ink, appearing to read "Elizabeth Gallenagh", is written over a light-colored background.

Elizabeth Gallenagh
Vice President, Government Affairs and General Counsel



The Honorable John D. Dingell

- 1) Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft, and intentional adulteration? If no, please explain why.**

Yes. The approach captured in H.R. 1919 requires members of the supply chain to verify suspect and illegitimate product and provides for greater assurances than under current law that the product is not counterfeit, stolen, or adulterated.

- 2) Do you agree that a traceability system would help to identify and detect illegitimate pharmaceuticals? If no, please explain why.**

Yes. H.R. 1919 requires manufacturers to include a product identifier on each package, which will assist supply chain partners in verifying if a product is legitimate.

- 3) Do you agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers? If no, please explain why.**

Yes. The application of product identifiers and a national approach to pharmaceutical traceability allows supply chain stakeholders to provide greater assurances to patients and consumers that prescription medicines are safe.

- 4) Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns? If no, please explain why.**

Yes. A national approach to pedigree and traceability will help facilitate more efficient identification of recalled product and faster removal from the supply chain. Additionally, unique identification of products will add more security and certainty to the returns process. Under the current legislation, wholesale distributors will be verifying all returns to ensure legitimacy.

- 5) Do you agree that a traceability system should be based on uniform, national standards? If no, please explain why.**

Yes. The current patchwork of varying state laws not only creates operational challenges, but also leaves openings for bad actors to shop around for more lenient state rules — openings that could mean the difference between a fake or diverted medicine being dispensed or administered to an innocent patient in need of treatment. Because of this state-by-state variation, we believe that pedigree and traceability should be under the purview of Congress and the FDA and based on uniform, national standards.

6) Do you agree that a traceability system should include participation from everyone in the supply chain? Please explain why.

Yes. HDMA believes that all stakeholders - including manufacturers, distributors, and dispensers - should have a role in any traceability system. HDMA has been a leader in industry task forces and working groups that bring together manufacturers, distributors and pharmacies dedicated to identifying the operational and technical requirements for traceability implementation. HDMA is also an active member of PDSA, the Pharmaceutical Distribution Security Alliance, which has included members of the entire supply chain in the formulation, development and implementation of a traceability proposal.

7) Do you agree that a traceability system should take a phased-in approach? If no, please explain why.

Yes. Once product is serialized, it is believed that product traceability initially can be achieved at the lot level, with potential for traceability at a more discrete level as systems mature. A system that works for all supply chain partners across all 50 states cannot be achieved with the flip of a switch. The industry believes in working to achieve this goal but it needs to be accomplished in a measured, practical way, over time.

8) Do you agree that a traceability system with a phased-in approach should include clear requirements and a clear timeframe for a second phase? If no, please explain why.

Yes. HDMA supports a migration toward traceability at unit level that includes deliberate, careful evaluation and assessment by FDA and stakeholders at each step. As a result, exchange of transaction data will be possible and can be leveraged to provide additional efficiency and safety benefits within the supply chain.

9) Do you believe that a unit level traceability system is feasible at this time for all members of your industry? Please explain why.

No. It is critical that federal legislation be enacted to provide the appropriate targets and parameters for longer-term electronic solutions that HDMA members can then work to implement over the period of several years. Without a uniform, national pedigree and traceability law for all supply chain participants, it would not be feasible to implement a unit level traceability system.

10) Do you believe that a lot level traceability system is feasible at this time for all members of your industry? Please explain why.

No. Currently lot numbers on pharmaceutical products are not applied uniformly. Because of the complexities of a national supply chain, without federal standards, it would not be feasible for pharmaceutical distributors to implement a lot level traceability system.

11) Do you agree that the goal of any federal traceability system should be unit level tracing? If no, please explain why.

Yes. Currently, there is no mechanism to identify a unique bottle of medicine or distinguish one from another. H.R. 1919 will require manufacturers to apply a unique identifier to prescription drugs at the unit and case levels. This will facilitate improved ability to identify non-legitimate items and help protect the supply chain from counterfeit, adulterated or substandard products. Prescription drugs will be identified and traced at the unit and case level using a serial number (SNI), lot number and expiration date.

12) Do you believe that it is imperative that traceability legislation be passed this year? If no, please explain why.

Yes. It is critical that Congress act now due to the uncertainties faced by the industry, the need for uniformity across the supply chain and to ensure patient access to safe medicines in the U.S.



June 14, 2013

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
420 Cannon House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
237 Cannon House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone,

GPhA would like to submit the following in response to your recent additional questions for the record for the hearing before the Subcommittee on Health on Thursday, April 25, 2013, entitled "Securing Our Nation's Prescription Drug Supply Chain."

The Honorable John D. Dingell

1. **Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft, and intentional adulteration? If no, please explain why.**

Yes

2. **Do you agree that a traceability system would help to identify and detect illegitimate pharmaceuticals? If no, please explain why.**

Yes

3. **Do you agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers? If no, please explain why.**

Yes

4. **Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns? If no, please explain why.**

Yes

5. **Do you agree that a federal traceability system should be based on uniform, national standards? If no, please explain why.**

Yes

6. **Do you agree that a federal traceability system should include participation**

from everyone in the supply chain? Please explain why.

Yes. In order to prevent the introduction of counterfeit or adulterated products into the supply chain and ensure patient safety, it is vital that a federal traceability system is practical, focused, and uniform across the country and includes participation from everyone in the supply chain. It is for this reason that GPhA is a member of the Pharmaceutical Distribution Security Alliance, a multi-stakeholder initiative whose membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies.

- 7. Do you agree that a federal traceability system should take a phased-in approach? If no, please explain why.**

Yes

- 8. Do you agree that a federal traceability system with a phased-in approach should include clear requirements and a clear timeframe for a second phase? If no, please explain why.**

Yes

- 9. Do you believe that a unit level traceability system is feasible at this time for all members of your industry? Please explain why.**

No. At the present time, the technology to support a unit-level traceability system is unreliable and underdeveloped, and the costs associated with such a model would be billions of dollars. An attempt to implement such a system hastily and before the technology is developed would lead to confusion in the supply chain, aggravate product shortages, and dramatically increase costs for all prescriptions, particularly generic medicines.

- 10. Do you believe that a lot level traceability system is feasible at this time for all members of your industry? Please explain why.**

Yes. A lot-level traceability system is feasible and achievable for our industry in the near-term. Generic manufacturers have committed to identifying individual saleable units of medicine with labels, and maintaining and managing data in their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of products. Such a building-block approach would ensure orderly implementation and avoid unintended consequences, while allowing the industry to apply the knowledge and experience gained over time to refine the system as public health threats, interoperability standards, and technologies evolve.

- 11. Do you agree that the goal of any federal traceability system should be unit**

level tracing? If no, please explain why.

Yes

12. Do you believe that it is imperative that traceability legislation be passed this year? If no, please explain why.

Yes

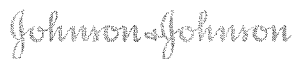
Thank you again for the opportunity to testify before the Subcommittee.

Sincerely,

A handwritten signature in dark ink, appearing to read 'C. Simmon'.

Christine Simmon
Senior Vice President, Policy and Strategic Alliances

cc: The Honorable John D. Dingell



June 10, 2013

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Representative Joseph Pitts,

First, let me thank you for your follow up questions regarding my testimony to the Subcommittee on Health on April 25, 2013 at the hearing entitled "Securing Our Nation's Prescription Drug Supply Chain."

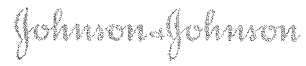
If Congress fails to act and the California law goes into effect, there will remain "numerous holes" and opportunities for bad actors to introduce "counterfeit or fraudulent product" into the nation-wide pharmaceutical supply chain. Prescription pharmaceutical products that are approved by the FDA for sale in the United States are manufactured and packaged to be sold anywhere in our nation through our authorized distributors of record (ADR's) and entities licensed by the state. Specifically, prescription pharmaceutical products are not manufactured or labeled for one specific state.

When a manufacturer sells a product to a wholesaler, pharmacy, hospital, or clinic for distribution and ultimately dispensing to the patient, the ownership, title and control of the product moves from the manufacturer to the commercial entity who purchased the product from the manufacturer. This commercial entity can distribute the product anywhere across the United States to other entities licensed by the state. Counterfeit product is introduced into the US supply chain through these entities, all of whom are beyond the manufacturer's control.

It is important that all entities engaged in the manufacturing, distributing, repackaging, and dispensing of prescription pharmaceutical products across the entire country be held accountable to ensure that all patients receive genuine product

If Congress fails to act and only the California law goes into effect, we will code our products accordingly and sell them in all states. Outside of California, if the downstream supply chain entities do not participate in the in system, the product identifiers will have little effect or benefit in protecting the public. Within California, patients will still be at risk due to the national scope of the drug supply. For example, the counterfeit Avastin situation could still occur again with counterfeit product being distributed into the state of California from another state, thereby, placing all patients at risk – including patients in California.

A single uniform, national standard for serialization and traceability will help protect the US prescription pharmaceutical supply chain. A patchwork of inconsistent state regulations is an ineffective means to protect the citizens of all states – including patients in California – from counterfeit product. Serialization and traceability will provide an additional deterrent against bad actors from trying to introduce counterfeit or fraudulent product into our nation's drug supply.



I hope the above detail has satisfactorily answered your questions. If not, I would be glad to provide further information.

Again, thank you for your personal interest in this matter. We look forward to Congress' action on this vital issue of patient safety.

Mike Rose
VP Supply Chain Visibility
Johnson & Johnson

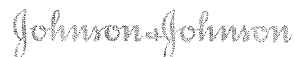
Johnson & Johnson

June 11, 2013

The Honorable John D. Dingell
Energy and Commerce Committee
2328 Rayburn House Office Building
Washington, DC 20515-6115

Dear Representative Dingell,

1. Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft, and intentional adulteration? If no, please explain why. YES
2. Do you agree that a traceability system would help to identify and detect illegitimate pharmaceuticals? If no, please explain why. YES
3. Do you agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers? If no, please explain why. YES
4. Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns? If no, please explain why. YES
5. Do you agree that a federal traceability system should be based on uniform, national standards? If no, please explain why. YES
6. Do you agree that a federal traceability system should include participation from everyone in the supply chain? Please explain why. YES
7. Do you agree that a federal traceability system should take a phased-in approach? If no, please explain why. YES
8. Do you agree that a federal traceability system with a phased-in approach should include clear requirements and a clear timeframe for a second phase? If no, please explain why. YES
9. Do you believe that a unit level traceability system is feasible at this time for all members of your industry? Please explain why. YES
The necessary standards, technologies and know how have advanced sufficient to make a unit level traceability system feasible. However, all supply chain stakeholders will need to make significant investments to implement unit level traceability.



10. Do you believe that a lot level traceability system is feasible at this time for all members of your industry? Please explain why. YES

Manufacturers control their production and product inventory by lot today. Lot control is an accepted and well understood practice by the FDA. Manufacturers include product lot information on the shipping documentation that accompanies every shipment made by a manufacturer to their customer. When a problem(s) is identified with a product, the specific lots affected by the problem are identified. If the problem(s) is significant enough to warrant a recall, then only these specific lots would be withdrawn or recalled from the market. However, it is important to note that, currently, wholesalers and pharmacies do not control their inventories by lot. Therefore, wholesalers and pharmacies would have to make significant investments to implement lot level traceability.

11. Do you agree that the goal of any federal traceability system should be unit level tracing? If no, please explain why. YES

12. Do you believe that it is imperative that traceability legislation be passed this year? If no, please explain why. YES

Best regards,

Mike Rose
VP Supply Chain Visibility
Johnson & Johnson

Responses to the Questions for the Record letter by Mr. Tim Davis

The Honorable John D. Dingell

1. Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft, and intentional adulteration? If no, please explain why.
Yes.
2. Do you agree that a traceability system would help to identify and detect illegitimate pharmaceuticals? If no, please explain why.
Yes.
3. Do you agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers? If no, please explain why.
Yes.
4. Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns? If no, please explain why.
Yes
5. Do you agree that a federal traceability system should be based on uniform, national standards? If no, please explain why.
Yes.
6. Do you agree that a federal traceability system should include participation from everyone in the supply chain? Please explain why.
Yes.
7. Do you agree that a federal traceability system should take a phased-in approach? If no, please explain why.
Yes, I very strongly agree that a federal traceability system should take a phased-in approach.
8. Do you agree that a federal traceability system with a phased-in approach should include clear requirements and a clear timeframe for a second phase? If no, please explain why.
Yes.
9. Do you believe that a unit level traceability system is feasible at this time for all members of your industry? Please explain why.
No, I do not believe that a unit level traceability system is feasible at this time for most of our members. While the overall hardware and software components exist in

distinctly separate resources, there has not been an aggregated solution specific to the practice of pharmacy comprised of these distinct components found in the marketplace today. To compile the required resources, adjust workflow, integrate solutions, and account for all pharmacy level exceptions to optimal processing scenarios will take time and experience. A requirement of unit level traceability at this point in time will compromise patient care and safety by creating turmoil and confusion through the use on an incomplete solution. Finally, while we hope that the technology develops quickly enough so it can exist in the market long enough to be inexpensive for our small business owners – it is not there yet so that remains an unknown.

10. Do you agree that the goal of any federal traceability system should be unit level tracing? If no, please explain why.
Yes, I agree that the ultimate goal of any federal traceability system should be unit level tracing.
11. Do you believe that it is imperative that traceability legislation be passed this year? If no, please explain why.
Yes.